Disability Evaluation Under Social Security

(Also known as the "Blue Book")

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Office of Disability Programs

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Listing of Impairments – Part A

The following sections in Part A are applicable to individuals age 18 and over and to children under age 18 where criteria are appropriate

This electronic version contains the new Skin Disorders and Malignant Neoplastic Diseases listings and related criteria that became effective July 9, 2004, and December 15, 2004, respectively.

1.00 Musculoskeletal System

A. Disorders of the musculoskeletal system may result from hereditary, congenital, or acquired pathologic processes. Impairments may result from infectious, inflammatory, or degenerative processes, traumatic or developmental events, or neoplastic, vascular, or toxic/metabolic diseases.

B. Loss of function.

1. *General*. Under this section, loss of function may be due to bone or joint deformity or destruction from any cause; miscellaneous disorders of the spine with or without radiculopathy or other neurological deficits; amputation; or fractures or soft tissue injuries, including burns, requiring prolonged periods of immobility or convalescence. For inflammatory arthritides that may result in loss of function because of inflammatory peripheral joint or axial arthritis or sequelae, or because of extra-articular features, see 14.00B6. Impairments with neurological causes are to be evaluated under 11.00ff.

2. *How we define loss of function in these listings*.

a. *General*. Regardless of the cause(s) of a musculoskeletal impairment, functional loss for purposes of these listings is defined as the inability to ambulate effectively on a sustained basis for any reason, including pain associated with the underlying musculoskeletal impairment, or the inability to perform fine and gross movements effectively on a sustained basis for any reason, including pain associated with the underlying musculoskeletal impairment. The inability to ambulate effectively or the inability to perform fine and gross movements effectively must have lasted, or be expected to last, for at least 12 months. For the purposes of these criteria, consideration of the ability to perform these activities must be from a physical standpoint alone. When there is an inability to perform these activities due to a mental impairment, the criteria in 12.00ff are to be used. We will determine whether an individual can ambulate effectively or can perform fine and gross movements effectively based on the medical and other evidence in the case record, generally without developing additional evidence about the individual's ability to perform the specific activities listed as examples in 1.00B2b(2) and 1.00B2c.

b. *What we mean by inability to ambulate effectively*.

(1) *Definition*. Inability to ambulate effectively means an extreme limitation of the ability to walk; i.e., an impairment(s) that interferes very seriously with the individual's ability to independently initiate, sustain, or complete activities. Ineffective ambulation is defined generally as having insufficient lower extremity functioning (see 1.00J) to permit independent ambulation without the use of a hand-held assistive device(s) that limits the functioning
of both upper extremities. (Listing 1.05C is an exception to this general definition because the individual has the use of only one upper extremity due to amputation of a hand.)

(2) *To ambulate effectively*, individuals must be capable of sustaining a reasonable walking pace over a sufficient distance to be able to carry out activities of daily living. They must have the ability to travel without companion assistance to and from a place of employment or school. Therefore, examples of ineffective ambulation include, but are not limited to, the inability to walk without the use of a walker, two crutches or two canes, the inability to walk a block at a reasonable pace on rough or uneven surfaces, the inability to use standard public transportation, the inability to carry out routine ambulatory activities, such as shopping and banking, and the

inability to climb a few steps at a reasonable pace with the use of a single hand rail. The ability to walk independently about one's home without the use of assistive devices does not, in and of itself, constitute effective ambulation.

c. *What we mean by inability to perform fine and gross movements effectively*. Inability to perform fine and gross movements effectively means an extreme loss of function of both upper extremities; i.e., an impairment(s) that interferes very seriously with the individual's ability to independently initiate, sustain, or complete activities. To use their upper extremities effectively, individuals must be capable of sustaining such functions as reaching, pushing, pulling, grasping, and fingering to be able to carry out activities of daily living. Therefore, examples of inability to perform fine and gross movements effectively include, but are not limited to, the inability to prepare a simple meal and feed oneself, the inability to take care of personal hygiene, the inability to sort and handle papers or files, and the inability to place files in a file cabinet at or above waist level.

d. *Pain or other symptoms*. Pain or other symptoms may be an important factor contributing to functional loss. In order for pain or other symptoms to be found to affect an individual's ability to perform basic work activities, medical signs or laboratory findings must show the existence of a medically determinable impairment(s) that could reasonably be expected to produce the pain or other symptoms. The musculoskeletal listings that include pain or other symptoms among their criteria also include criteria for limitations in functioning as a result of the listed impairment, including limitations caused by pain. It is, therefore, important to evaluate the intensity and persistence of such pain or other symptoms carefully in order to determine their impact on the individual's functioning under these listings. See also §§ 404.1525(f) and 404.1529 of this part, and §§ 416.925(f) and 416.929 of part 416 of this chapter.

C. Diagnosis and evaluation.

1. *General*. Diagnosis and evaluation of musculoskeletal impairments should be supported, as applicable, by detailed descriptions of the joints, including ranges of motion, condition of the musculature (e.g., weakness, atrophy), sensory or reflex changes, circulatory deficits, and laboratory findings, including findings on x-ray or other appropriate medically acceptable imaging. Medically acceptable imaging includes, but is not limited to, x-ray imaging, computerized axial tomography (CAT scan) or magnetic resonance imaging (MRI), with or without contrast material, myelography, and radionuclear bone scans. "Appropriate" means that the technique used is the proper one to support the evaluation and diagnosis of the impairment.

2. *Purchase of certain medically acceptable imaging*. While any appropriate medically acceptable imaging is useful in establishing the diagnosis of musculoskeletal impairments, some tests, such as CAT scans and MRIs, are quite expensive, and we will not routinely purchase them. Some, such as myelograms, are invasive and may involve significant risk. We will not order such tests. However, when the results of any of these tests are part of the existing evidence in the case record we will consider them together with the other relevant evidence.

3. *Consideration of electrodiagnostic procedures*. Electrodiagnostic procedures may be useful in establishing the clinical diagnosis, but do not constitute alternative criteria to the requirements of 1.04.

D. The physical examination must include a detailed description of the rheumatological, orthopedic, neurological, and other findings appropriate to the specific impairment being evaluated. These physical findings must be determined on the basis of objective observation

during the examination and not simply a report of the individual's allegation; e.g., “He says his leg is weak, numb.” Alternative testing methods should be used to verify the abnormal findings; e.g., a seated straight-leg raising test in addition to a supine straight-leg raising test. Because abnormal physical findings may be intermittent, their presence over a period of time must be established by a record of ongoing management and evaluation. Care must be taken to ascertain that the reported examination findings are consistent with the individual's daily activities.

E. Examination of the spine.

1. *General*. Examination of the spine should include a detailed description of gait, range of motion of the spine given quantitatively in degrees from the vertical position (zero degrees) or, for straight-leg raising from the sitting and supine position (zero degrees), any other appropriate tension signs, motor and sensory abnormalities, muscle spasm, when present, and deep tendon reflexes. Observations of the individual during the examination should be reported; e.g., how he or she gets on and off the examination table. Inability to walk on the heels or toes, to squat, or to arise from a squatting position, when appropriate, may be considered evidence of significant motor loss. However, a report of atrophy is not acceptable as evidence of significant motor loss without circumferential measurements of both thighs and lower legs, or both upper and lower arms, as appropriate, at a stated point above and below the knee or elbow given in inches or centimeters. Additionally, a report of atrophy should be accompanied by measurement of the strength of the muscle(s) in question generally based on a grading system of 0 to 5, with 0 being complete loss of strength and 5 being maximum strength. A specific description of atrophy of hand muscles is acceptable without measurements of atrophy but should include measurements of grip and pinch strength.

2. *When neurological abnormalities persist*. Neurological abnormalities may not completely subside after treatment or with the passage of time. Therefore, residual neurological abnormalities that persist after it has been determined clinically or by direct surgical or other observation that the ongoing or progressive condition is no longer present will not satisfy the required findings in 1.04. More serious neurological deficits (paraparesis, paraplegia) are to be evaluated under the criteria in 11.00ff.

F. Major joints refers to the major peripheral joints, which are the hip, knee, shoulder, elbow, wrist-hand, and ankle-foot, as opposed to other peripheral joints (e.g., the joints of the hand or forefoot) or axial joints (i.e., the joints of the spine.) The wrist and hand are considered together as one major joint, as are the ankle and foot. Since only the ankle joint, which consists of the juncture of the bones of the lower leg (tibia and fibula) with the hindfoot (tarsal bones), but not the forefoot, is crucial to weight bearing, the ankle and foot are considered separately in evaluating weight bearing.

G. Measurements of joint motion are based on the techniques described in the chapter on the extremities, spine, and pelvis in the current edition of the "Guides to the Evaluation of Permanent Impairment" published by the American Medical Association.

H. Documentation.

1. *General*. Musculoskeletal impairments frequently improve with time or respond to treatment. Therefore, a longitudinal clinical record is generally important for the assessment of severity and expected duration of an impairment unless the claim can be decided favorably on the basis of the current evidence.

2. *Documentation of medically prescribed treatment and response*. Many individuals, especially those who have listing-level impairments, will have received the benefit of medically prescribed treatment. Whenever evidence of such treatment is available it must be considered.

3. *When there is no record of ongoing treatment*. Some individuals will not have received ongoing treatment or have an ongoing relationship with the medical community despite the existence of a severe impairment(s). In such cases, evaluation will be made on the basis of the current objective medical evidence and other available evidence, taking into consideration the individual's medical history, symptoms, and medical source opinions. Even though an individual who does not receive treatment may not be able to show an impairment that meets the criteria of one of the musculoskeletal listings, the individual may have an impairment(s) equivalent in severity to one of the listed impairments or be disabled based on consideration of his or her residual functional capacity (RFC) and age, education and work experience.

4. *Evaluation when the criteria of a musculoskeletal listing are not met*. These listings are only examples of common musculoskeletal disorders that are severe enough to prevent a person from engaging in gainful activity. Therefore, in any case in which an individual has a medically determinable impairment that is not listed, an impairment that does not meet the requirements of a listing, or a combination of impairments no one of which meets the requirements of a listing, we will consider medical equivalence. (See §§ 404.1526 and 416.926.) Individuals who have an impairment(s) with a level of severity that does not meet or equal the criteria of the musculoskeletal listings may or may not have the RFC that would enable them to engage in substantial gainful activity. Evaluation of the impairment(s) of these individuals should proceed through the final steps of the sequential evaluation process in §§ 404.1520 and 416.920 (or, as appropriate, the steps in the medical improvement review standard in §§ 404.1594 and 416.994).

I. Effects of treatment.

1. *General*. Treatments for musculoskeletal disorders may have beneficial effects or adverse side effects. Therefore, medical treatment (including surgical treatment) must be considered in terms of its effectiveness in ameliorating the signs, symptoms, and laboratory abnormalities of the disorder, and in terms of any side effects that may further limit the individual.

2. *Response to treatment*. Response to treatment and adverse consequences of treatment may vary widely. For example, a pain medication may relieve an individual's pain completely, partially, or not at all. It may also result in adverse effects, e.g., drowsiness, dizziness, or disorientation that compromise the individual's ability to function. Therefore, each case must be considered on an individual basis, and include consideration of the effects of treatment on the individual's ability to function.

3. *Documentation*. A specific description of the drugs or treatment given (including surgery), dosage, frequency of administration, and a description of the complications or response to treatment should be obtained. The effects of treatment may be temporary or long-term. As such, the finding regarding the impact of treatment must be based on a sufficient period of treatment to permit proper consideration or judgment about future functioning.

J. Orthotic, prosthetic, or assistive devices.

1. *General*. Consistent with clinical practice, individuals with musculoskeletal impairments may be examined with and without the use of any orthotic, prosthetic, or assistive devices as explained in this section.

2. *Orthotic devices*. Examination should be with the orthotic device in place and should include an evaluation of the individual's maximum ability to function effectively with the orthosis. It is unnecessary to routinely evaluate the individual's ability to function without the orthosis in place. If the individual has difficulty with, or is unable to use, the orthotic device, the medical basis for the difficulty should be documented. In such cases, if the impairment involves a lower extremity or extremities, the examination should include information on the individual's ability to ambulate effectively without the device in place unless contraindicated by the medical judgment of a physician who has treated or examined the individual.

3. *Prosthetic devices*. Examination should be with the prosthetic device in place. In amputations involving a lower extremity or extremities, it is unnecessary to evaluate the individual's ability to walk without the prosthesis in place. However, the individual's medical ability to use a prosthesis to ambulate effectively, as defined in 1.00B2b, should be evaluated. The condition of the stump should be evaluated without the prosthesis in place.

4. *Hand-held assistive devices*. When an individual with an impairment involving a lower extremity or extremities uses a hand-held assistive device, such as a cane, crutch or walker, examination should be with and without the use of the assistive device unless contraindicated by the medical judgment of a physician who has treated or examined the individual. The individual's ability to ambulate with and without the device provides information as to whether, or the extent to which, the individual is able to ambulate without assistance. The medical basis for the use of any assistive device (e.g., instability, weakness) should be documented. The requirement to use a hand-held assistive device may also impact on the individual's functional capacity by virtue of the fact that one or both upper extremities are not available for such activities as lifting, carrying, pushing, and pulling.

K. Disorders of the spine, listed in 1.04, result in limitations because of distortion of the bony and ligamentous architecture of the spine and associated impingement on nerve roots (including the cauda equina) or spinal cord. Such impingement on nerve tissue may result from a herniated nucleus pulposus, spinal stenosis, arachnoiditis, or other miscellaneous conditions. Neurological abnormalities resulting from these disorders are to be evaluated by referral to the neurological listings in 11.00ff, as appropriate. (See also 1.00B and E.)

1. *Herniated nucleus pulposus* is a disorder frequently associated with the impingement of a nerve root. Nerve root compression results in a specific neuro-anatomic distribution of symptoms and signs depending upon the nerve root(s) compromised.

2. *Spinal arachnoiditis*.

a. *General*. Spinal arachnoiditis is a condition characterized by adhesive thickening of the arachnoid which may cause intermittent ill-defined burning pain and sensory dysesthesia, and may cause neurogenic bladder or bowel incontinence when the cauda equina is involved.

b. *Documentation*. Although the cause of spinal arachnoiditis is not always clear, it may be associated with chronic compression or irritation of nerve roots (including the cauda equina) or the spinal cord. For example, there may be evidence of spinal stenosis, or a history of spinal trauma or meningitis. Diagnosis must be confirmed at the time of surgery by gross description, microscopic examination of biopsied tissue, or by findings on appropriate medically acceptable imaging. Arachnoiditis is sometimes used as a diagnosis when such a diagnosis is unsupported by clinical or laboratory findings. Therefore, care must be taken to ensure that the diagnosis is

documented as described in 1.04B. Individuals with arachnoiditis, particularly when it involves the lumbosacral spine, are generally unable to sustain any given position or posture for more than a short period of time due to pain.

3. *Lumbar spinal stenosis* is a condition that may occur in association with degenerative processes, or as a result of a congenital anomaly or trauma, or in association with Paget's disease of the bone. *Pseudoclaudication*, which may result from lumbar spinal stenosis, is manifested as pain and weakness, and may impair ambulation. Symptoms are usually bilateral, in the low back, buttocks, or thighs, although some individuals may experience only leg pain and, in a few cases, the leg pain may be unilateral. The pain generally does not follow a particular neuro-anatomical distribution, i.e., it is distinctly different from the radicular type of pain seen with a herniated intervertebral disc, is often of a dull, aching quality, which may be described as "discomfort" or an "unpleasant sensation," or may be of even greater severity, usually in the low back and radiating into the buttocks region bilaterally. The pain is provoked by extension of the spine, as in walking or merely standing, but is reduced by leaning forward. The distance the individual has to walk before the pain comes on may vary. Pseudoclaudication differs from peripheral vascular claudication in several ways. Pedal pulses and Doppler examinations are unaffected by pseudoclaudication. Leg pain resulting from peripheral vascular claudication involves the calves, and the leg pain in vascular claudication is ordinarily more severe than any back pain that may also be present. An individual with vascular claudication will experience pain after walking the same distance time after time, and the pain will be relieved quickly when walking stops.

4. *Other miscellaneous conditions* that may cause weakness of the lower extremities, sensory changes, areflexia, trophic ulceration, bladder or bowel incontinence, and that should be evaluated under 1.04 include, but are not limited to, osteoarthritis, degenerative disc disease, facet arthritis, and vertebral fracture. Disorders such as spinal dysrhaphism (e.g., spina bifida), diastematomyelia, and tethered cord syndrome may also cause such abnormalities. In these cases, there may be gait difficulty and deformity of the lower extremities based on neurological abnormalities, and the neurological effects are to be evaluated under the criteria in 11.00ff.

L. Abnormal curvatures of the spine. Abnormal curvatures of the spine (specifically, scoliosis, kyphosis and kyphoscoliosis) can result in impaired ambulation, but may also adversely affect functioning in body systems other than the musculoskeletal system. For example, an individual's ability to breathe may be affected; there may be cardiac difficulties (e.g., impaired myocardial function); or there may be disfigurement resulting in withdrawal or isolation. When there is impaired ambulation, evaluation of equivalence may be made by reference to 14.09A. When the abnormal curvature of the spine results in symptoms related to fixation of the dorsolumbar or cervical spine, evaluation of equivalence may be made by reference to 14.09B. When there is respiratory or cardiac involvement or an associated mental disorder, evaluation may be made under 3.00ff, 4.00ff, or 12.00ff, as appropriate. Other consequences should be evaluated according to the listing for the affected body system.

M. Under continuing surgical management, as used in 1.07 and 1.08, refers to surgical procedures and any other associated treatments related to the efforts directed toward the salvage or restoration of functional use of the affected part. It may include such factors as post-surgical procedures, surgical complications, infections, or other medical complications, related illnesses, or related treatments that delay the individual's attainment of maximum benefit from therapy. When burns are not under continuing surgical management, see 8.00F.

N. After maximum benefit from therapy has been achieved in situations involving fractures of an upper extremity (1.07), or soft tissue injuries (1.08), i.e., there have been no significant changes in physical findings or on appropriate medically acceptable imaging for any 6-month period after the last definitive surgical procedure or other medical intervention, evaluation must be made on the basis of the demonstrable residuals, if any. A finding that 1.07 or 1.08 is met must be based on a consideration of the symptoms, signs, and laboratory findings associated with recent or anticipated surgical procedures and the resulting recuperative periods, including any related medical complications, such as infections, illnesses, and therapies which impede or delay the efforts toward restoration of function. Generally, when there has been no surgical or medical intervention for 6 months after the last definitive surgical procedure, it can be concluded that maximum therapeutic benefit has been reached. Evaluation at this point must be made on the basis of the demonstrable residual limitations, if any, considering the individual's impairment-related symptoms, signs, and laboratory findings, any residual symptoms, signs, and laboratory findings associated with such surgeries, complications, and recuperative periods, and other relevant evidence.

O. Major function of the face and head, for purposes of listing 1.08, relates to impact on any or all of the activities involving vision, hearing, speech, mastication, and the initiation of the digestive process.

P. When surgical procedures have been performed, documentation should include a copy of the operative notes and available pathology reports.

Q. Effects of obesity. Obesity is a medically determinable impairment that is often associated with disturbance of the musculoskeletal system, and disturbance of this system can be a major cause of disability in individuals with obesity. The combined effects of obesity with musculoskeletal impairments can be greater than the effects of each of the impairments considered separately. Therefore, when determining whether an individual with obesity has a listing-level impairment or combination of impairments, and when assessing a claim at other steps of the sequential evaluation process, including when assessing an individual's residual functional capacity, adjudicators must consider any additional and cumulative effects of obesity.

1.01 Category of Impairments, Musculoskeletal

1.02 ***Major dysfunction of a joint(s) (due to any cause)***: Characterized by gross anatomical deformity (e.g., subluxation, contracture, bony or fibrous ankylosis, instability) and chronic joint pain and stiffness with signs of limitation of motion or other abnormal motion of the affected joint(s), and findings on appropriate medically acceptable imaging of joint space narrowing, bony destruction, or ankylosis of the affected joint(s). With:

A. Involvement of one major peripheral weight-bearing joint (i.e., hip, knee, or ankle), resulting in inability to ambulate effectively, as defined in 1.00B2b;

OR

B. Involvement of one major peripheral joint in each upper extremity (i.e., shoulder, elbow, or wrist-hand), resulting in inability to perform fine and gross movements effectively, as defined in 1.00B2c.

1.03 ***Reconstructive surgery or surgical arthrodesis of a major weight- bearing joint***, with inability to ambulate effectively, as defined in 1.00B2b, and return to effective ambulation did not occur, or is not expected to occur, within 12 months of onset.

1.04 ***Disorders of the spine*** (e.g., herniated nucleus pulposus, spinal arachnoiditis, spinal stenosis, osteoarthritis, degenerative disc disease, facet arthritis, vertebral fracture), resulting in compromise of a nerve root (including the cauda equina) or the spinal cord. With:

A. Evidence of nerve root compression characterized by neuro-anatomic distribution of pain, limitation of motion of the spine, motor loss (atrophy with associated muscle weakness or muscle weakness) accompanied by sensory or reflex loss and, if there is involvement of the lower back, positive straight-leg raising test (sitting and supine);

OR

B. Spinal arachnoiditis, confirmed by an operative note or pathology report of tissue biopsy, or by appropriate medically acceptable imaging, manifested by severe burning or painful dysesthesia, resulting in the need for changes in position or posture more than once every 2 hours;

OR

C. Lumbar spinal stenosis resulting in pseudoclaudication, established by findings on appropriate medically acceptable imaging, manifested by chronic nonradicular pain and weakness, and resulting in inability to ambulate effectively, as defined in 1.00B2b.

1.05 ***Amputation (due to any cause).***

A. Both hands;

OR

B. One or both lower extremities at or above the tarsal region, with stump complications resulting in medical inability to use a prosthetic device to ambulate effectively, as defined in 1.00B2b, which have lasted or are expected to last for at least 12 months;

OR

C. One hand and one lower extremity at or above the tarsal region, with inability to ambulate effectively, as defined in 1.00B2b;

OR

D. Hemipelvectomy or hip disarticulation.

1.06 ***Fracture of the femur, tibia, pelvis, or one or more of the tarsal bones.*** With:

A. Solid union not evident on appropriate medically acceptable imaging and not clinically solid;

AND

B. Inability to ambulate effectively, as defined in 1.00B2b, and return to effective ambulation did not occur or is not expected to occur within 12 months of onset.

1.07 ***Fracture of an upper extremity*** with nonunion of a fracture of the shaft of the humerus, radius, or ulna, under continuing surgical management, as defined in 1.00M, directed toward restoration of functional use of the extremity, and such function was not restored or expected to be restored within 12 months of onset.

1.08 ***Soft tissue injury (e.g., burns)*** of an upper or lower extremity, trunk, or face and head, under continuing surgical management, as defined in 1.00M, directed toward the salvage or restoration of major function, and such major function was not restored or expected to be restored within 12 months of onset. Major function of the face and head is described in 1.00O.

2.00 Special Senses And Speech

A. Disorders of Vision

1. *Causes of impairment.* Diseases or injury of the eyes may produce loss of visual acuity or loss of the peripheral field. Loss of visual acuity results in inability to distinguish detail and prevents reading and fine work. Loss of the peripheral field restricts the ability of an individual to move about freely. The extent of impairment of sight should be determined by visual acuity and peripheral field testing.

2. *Visual acuity.* A loss of visual acuity may result in impaired distant vision or near vision, or both. However, for you to meet the level of severity described in 2.02 and 2.04, only the remaining visual acuity for distance of the better eye with best correction based on the Snellen test chart measurement may be used. Correction obtained by special visual aids (e.g., contact lenses) will be considered if the individual has the ability to wear such aids.

3. *Field of vision*. Impairment of peripheral vision may result if there is contraction of the visual fields. The contraction may be either symmetrical or irregular. The extent of the remaining peripheral visual field will be determined by usual perimetric methods at a distance of 330 mm. under illumination of not less than 7-foot candles. For the phakic eye (the eye with a lens), a 3 mm. white disc target will be used, and for the aphakic eye (the eye without a lens), a 6 mm. white disc target will be used. In neither instance should corrective spectacle lenses be worn during the examination but if they have been used, this fact must be stated.

Measurements obtained on comparable perimetric devices may be used; this does not include the use of tangent screen measurements. For measurements obtained using the Goldmann perimeter, the object size designation III and the illumination designation 4 should be used for the phakic eye, and the object size designation IV and illumination designation 4 for the aphakic eye.

Field measurements must be accompanied by notated field charts, a description of the type and size of the target and the test distance. Tangent screen visual fields are not acceptable as a measurement of peripheral field loss.

Where the loss is predominantly in the lower visual fields, a system such as the weighted grid scale for perimetric fields as described by B. Esterman (see Grid for Scoring Visual Fields, II. Perimeter, *Archives of Ophthalmology, 79:400, 1968)* may be used for determining whether the visual field loss is comparable to that described in Table 2.

4. *Muscle function.* Paralysis of the third cranial nerve producing ptosis, paralysis of accommodation, and dilation and immobility of the pupil may cause significant visual impairment. When all the muscles of the eye are paralyzed including the iris and ciliary body (total ophthalmoplegia), the condition is considered a severe impairment provided it is bilateral. A finding of severe impairment based primarily on impaired muscle function must be supported by a report of an actual measurement of ocular motility.

5. *Visual efficiency.* Loss of visual efficiency may be caused by disease or injury resulting in a reduction of visual acuity or visual field. The visual efficiency of one eye is the product of the percentage of visual acuity efficiency and the percentage of visual field efficiency. (See Tables No. 1 and 2, following 2.09.)

6. *Special Situations.* Aphakia represents a visual handicap in addition to the loss of visual acuity. The term monocular aphakia would apply to an individual who has had the lens removed from one eye, and who still retains the lens in the other eye, or to an individual who has only one eye which is aphakic. The term binocular aphakia would apply to an individual who has had both lenses removed. In cases of binocular aphakia, the efficiency of the better eye will be accepted as *75* percent of its value. In cases of monocular aphakia, where the better eye is aphakic, the visual efficiency will be accepted as 50 percent of the value. (If an individual has binocular aphakia, and the visual acuity in the poorer eye can be corrected only to 20/200, or less, the visual efficiency of the better eye will be accepted as 50 percent of its value.)

Ocular symptoms of systemic disease may or may not produce a disabling visual impairment. These manifestations should be evaluated as part of the underlying disease entity by reference to the particular body system involved.

7. *Statutory Blindness.* The term "statutory blindness" refers to the degree of visual impairment which defines the term "blindness" in the Social Security Act. Both 2.02 and 2.03A and B denote statutory blindness.

B. Otolaryngology

1. *Hearing Impairment.* Hearing ability should be evaluated in terms of the person's ability to hear and distinguish speech.

Loss of hearing can be quantitatively determined by an audiometer which meets the standards of the American National Standards Institute (ANSI) for air and bone conducted stimuli (i.e., ANSI S 3.6-1969 and ANSI S 3.13-1972, or subsequent comparable revisions) and performing all hearing measurements in an environment which meets the ANSI standard for maximal permissible background sound (ANSI S 3.1-1977).

Speech discrimination should be determined using a standardized measure of speech discrimination ability in quiet at a test presentation level sufficient to ascertain maximum discrimination ability. The speech discrimination measure (test) used, and the level at which testing was done must be reported.

Hearing tests should be preceded by an otolaryngologic examination and should be performed by or under the supervision of an otolaryngologist or audiologist qualified to perform such tests.

In order to establish an independent medical judgment as to the level of impairment in a claimant alleging deafness, the following examinations should be reported: Otolaryngologic examination, pure tone air and bone audiometry, speech reception threshold (SRT), and speech discrimination testing. A copy of reports of medical examination and audiologic evaluations must be submitted.

Cases of alleged "deaf mutism" should be documented by a hearing evaluation. Records obtained from a speech and hearing rehabilitation center or a special school for the deaf may be acceptable, but if these reports are not available, or are found to be inadequate, a current hearing evaluation should be submitted as outlined in the preceding paragraph.

2. *Vertigo associated with disturbances of labyrinthine-vestibular function, including Meniere's disease.* These disturbances of balance are characterized by an hallucination of motion or a loss of position sense and a sensation of dizziness which may be constant or may occur in paroxysmal attacks. Nausea, vomiting, ataxia, and incapacitation are frequently observed, particularly during the acute attack. It is important to differentiate the report of rotary vertigo from that of "dizziness" which is described as light-headedness, unsteadiness, confusion, or syncope.

Meniere's disease is characterized by paroxysmal attacks of vertigo, tinnitus, and fluctuating hearing loss. Remissions are unpredictable and irregular, but may be long-lasting; hence, the severity of impairment is best determined after prolonged observation and serial reexaminations.

The diagnosis of a vestibular disorder requires a comprehensive neuro-otolaryngologic examination with a detailed description of the vertiginous episodes, including notation of frequency, severity, and duration of the attacks. Pure tone and speech audiometry with the appropriate special examinations, such as Bekesy audiometry, are necessary. Vestibular function is accessed by positional and caloric testing, preferably by electronystagmography. When polytomograms, contrast radiography, or other special tests have been performed, copies of the reports of these tests should be obtained in addition to appropriate medically acceptable imaging reports of the skull and temporal bone. Medically acceptable imaging includes, but is not limited to, x-ray imaging, computerized axial tomography (CAT scan) or magnetic resonance imaging (MRI), with or without contrast material, myelography, and radiocnuclear bone scans. "Appropriate" means that the technique used is the proper one to support the evaluation and diagnosis of the impairment.

3. *Loss of speech.* In evaluating the loss of speech, the ability to produce speech by any means includes the use of mechanical or electronic devices that improve voice or articulation. Impairments of speech may also be evaluated under the body system for the underlying disorder, such as neurological disorders, 11.00ff.

2.01 Category of Impairments, Special Senses and Speech

2.02 ***Impairment of Visual Acuity***. Remaining vision in the better eye after best correction is 20/200 or less.

2.03 ***Contraction of Peripheral Visual Fields in the Better Eye***.

A. To 10^{O} or less from the point of fixation; or

B. So the widest diameter subtends an angle no greater than 20 degrees; or

C. To 20 percent or less visual field efficiency.

2.04 ***Loss of visual efficiency***. The visual efficiency of the better eye after best correction is 20 percent or less. (The percent of remaining visual efficiency is equal to the product of the percent of remaining visual acuity efficiency and the percent of remaining visual field efficiency.)

2.05 (Reserved)

2.06 ***Total Bilateral Ophthalmoplegia***.

2.07 ***Disturbance of Labyrinthine- Vestibular Function*** (Including Meniere's disease), characterized by a history of frequent attacks of balance disturbance, tinnitus, and progressive loss of hearing. With both A and B:

A. Disturbed function of vestibular labyrinth demonstrated by caloric or other vestibular tests; and

B. Hearing loss established by audiometry.

2.08 ***Hearing Impairments*** (hearing not restorable by a hearing aid) manifested by:

A. Average hearing threshold sensitivity for air conduction of *90* decibels or greater, and for bone conduction to corresponding maximal levels, in the better ear, determined by the simple average of hearing threshold levels at 500, 1000, and 2000 hz. (see 2.00 B 1); or

B. Speech discrimination scores of 40 percent or less in the better ear.

2.09 L***oss of speech*** due to any cause, with inability to produce by any means speech that can be heard, understood, or sustained.

Table No.1. – Percentage of visual acuity efficiency corresponding to visual acuity notations for distance in the phakic and aphakic eye (better eye).

Snellen		Percent Visual Acuity Efficiency		
English	Metric	Phakic[1]	Aphakic Monocular[2]	Aphakic Binocular[3]
20/16	6/5	100	50	75
20/20	6/6	100	50	75
20/25	6/7.5	95	47	71
20/32	6/10	90	45	67
20/40	6/12	85	42	64
20/50	6/15	75	37	56
20/64	6/20	65	32	49
20/80	6/24	60	30	45
20/100	6/30	50	25	37
20/125	6/38	40	20	30
20/160	6/48	30	-	22
20/200	6/60	20	-	-

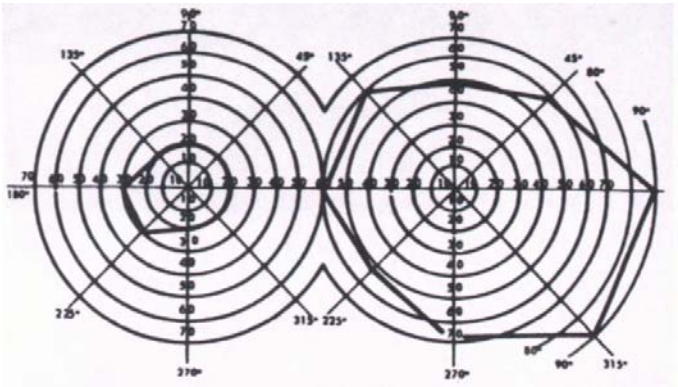
Column and Use

[1]Phakic.-1. A lens is present in both eyes. 2. A lens is present in the better eye and absent in the poorer eye. 3. A lens is present in one eye and the other eye is enucleated.

[2]Monocular.-1. A lens is absent in the better eye and present in the poorer eye. 2. The lenses are absent in both eyes; however, the visual acuity in the poorer eye after best correction is 20/200 or less. 3. A lens is absent from one eye and the other eye is enucleated.

[3]Binocular.-1. The lenses are absent from both eyes and the visual acuity in the poorer eye after best correction is greater than 20/200.

Table No. 2. – Chart of visual field showing extent of normal field and method of computing percent of visual field efficiency.



Left Eye (O.S.) Right Eye (O.D.)

1. Diagram of right eye illustrates extent of normal visual field as tested on standard perimeter at 3/330 (3 mm. white disc at a distance of 330 mm.) under 7 foot-candles illumination. The sums of the eight principal meridians of this field total 500 degrees.

2. The percent of visual field efficiency is obtained by adding the number of degrees of the eight principal meridians of the contracted field and dividing by 500. Diagram of left eye illustrates visual field contracted to 30 degrees in the temporal and down and out meridians and to 20 degrees in the remaining six meridians. The percent of visual field efficiency of this field is: 6x20 + 2x30 = 180 divided by 500 = 0.36 or 36 percent remaining visual field efficiency, or 64 percent loss.

3.00 Respiratory System

A. *Introduction.* The listings in this section describe impairments resulting from respiratory disorders based on symptoms, physical signs, laboratory test abnormalities, and response to a regimen of treatment prescribed by a treating source. Respiratory disorders along with any associated impairment(s) must be established by medical evidence. Evidence must be provided in sufficient detail to permit an independent reviewer to evaluate the severity of the impairment.

Many individuals, especially those who have listing-level impairments, will have received the benefit of medically prescribed treatment. Whenever there is evidence of such treatment, the longitudinal clinical record must include a description of the treatment prescribed by the treating

source and response in addition to information about the nature and severity of the impairment. It is important to document any prescribed treatment and response, because this medical management may have improved the individual's functional status. The longitudinal record should provide information regarding functional recovery, if any.

Some individuals will not have received ongoing treatment or have an ongoing relationship with the medical community, despite the existence of a severe impairment(s). An individual who does not receive treatment may or may not be able to show the existence of an impairment that meets the criteria of these listings. Even if an individual does not show that his or her impairment meets the criteria of these listings, the individual may have an impairment(s) equivalent in severity to one of the listed impairments or be disabled because of a limited residual functional capacity. Unless the claim can be decided favorably on the basis of the current evidence, a longitudinal record is still important because it will provide information about such things as the ongoing medical severity of the impairment, the level of the individual's functioning, and the frequency, severity, and duration of symptoms. Also, the asthma listing specifically includes a requirement for continuing signs and symptoms despite a regimen of prescribed treatment.

Impairments caused by chronic disorders of the respiratory system generally produce irreversible loss of pulmonary function due to ventilatory impairments, gas exchange abnormalities, or a combination of both. The most common symptoms attributable to these disorders are dyspnea on exertion, cough, wheezing, sputum production, hemoptysis, and chest pain. Because these symptoms are common to many other diseases, a thorough medical history, physical examination, and chest x-ray or other appropriate imaging technique are required to establish chronic pulmonary disease. Pulmonary function testing is required to assess the severity of the respiratory impairment once a disease process is established by appropriate clinical and laboratory findings.

Alterations of pulmonary function can be due to obstructive airway disease (e.g., emphysema, chronic bronchitis, asthma), restrictive pulmonary disorders with primary loss of lung volume (e.g., pulmonary resection, thoracoplasty, chest cage deformity as in kyphoscoliosis or obesity), or infiltrative interstitial disorders (e.g., diffuse pulmonary fibrosis). Gas exchange abnormalities without significant airway obstruction can be produced by interstitial disorders. Disorders involving the pulmonary circulation (e.g., primary pulmonary hypertension, recurrent thromboembolic disease, primary or secondary pulmonary vasculitis) can produce pulmonary vascular hypertension and, eventually, pulmonary heart disease (cor pulmonale) and right heart failure. Persistent hypoxemia produced by any chronic pulmonary disorder also can result in chronic pulmonary hypertension and right heart failure. Chronic infection, caused most frequently by mycobacterial or mycotic organisms, can produce extensive and progressive lung destruction resulting in marked loss of pulmonary function. Some disorders, such as bronchiectasis, cystic fibrosis, and asthma, can be associated with intermittent exacerbations of such frequency and intensity that they produce a disabling impairment, even when pulmonary function during periods of relative clinical stability is relatively well-maintained.

Respiratory impairments usually can be evaluated under these listings on the basis of a complete medical history, physical examination, a chest x-ray or other appropriate imaging techniques, and spirometric pulmonary function tests. In some situations, most typically with a diagnosis of diffuse interstitial fibrosis or clinical findings suggesting cor pulmonale, such as cyanosis or secondary polycythemia, an impairment may be underestimated on the basis of spirometry alone. More sophisticated pulmonary function testing may then be necessary to determine if gas exchange abnormalities contribute to the severity of a respiratory impairment. Additional testing might include measurement of diffusing capacity of the lungs for carbon monoxide or resting arterial blood gases. Measurement of arterial blood gases during exercise is required infrequently.

In disorders of the pulmonary circulation, right heart catheterization with angiography and/or direct measurement of pulmonary artery pressure may have been done to establish a diagnosis and evaluate severity. When performed, the results of the procedure should be obtained. Cardiac catheterization will not be purchased.

These listings are examples of common respiratory disorders that are severe enough to prevent a person from engaging in a gainful activity. When an individual has a medically-determinable impairment that is not listed, an impairment which does not meet a listing, or a combination of impairments no one of which meets a listing, we will consider whether the individual's impairment or combination of impairments is medically equivalent in severity to a listed impairment. Individuals who have an impairment(s) with a level of severity which does not meet or equal the criteria of the listings may or may not have the residual functional capacity (RFC) which would enable them to engage in substantial gainful activity. Evaluation of the impairment(s) of these individuals will proceed through the final steps of the sequential evaluation process.

B. *Mycobacterial, mycotic, and other chronic persistent infections of the* lung. These disorders are evaluated on the basis of the resulting limitations in pulmonary function. Evidence of chronic infections, such as active mycobacterial diseases or mycoses with positive cultures, drug resistance, enlarging parenchymal lesions, or cavitation, is not, by itself, a basis for determining that an individual has a disabling impairment expected to last 12 months. In those unusual cases of pulmonary infection that persist for a period approaching 12 consecutive months, the clinical findings, complications, therapeutic considerations, and prognosis must be carefully assessed to determine whether, despite relatively well-maintained pulmonary function, the individual nevertheless has an impairment that is expected to last for at least 12 consecutive months and prevent gainful activity.

C. *Episodic respiratory disease.* When a respiratory impairment is episodic in nature, as can occur with exacerbations of asthma, cystic fibrosis, bronchiectasis, or chronic asthmatic bronchitis, the frequency and intensity of episodes that occur despite prescribed treatment are often the major criteria for determining the level of impairment. Documentation for these exacerbations should include available hospital, emergency facility and/or physician records indicating the dates of treatment; clinical and laboratory findings on presentation, such as the results of spirometry and arterial blood gas studies (ABGS); the treatment administered; the time period required for treatment; and the clinical response. Attacks of asthma, episodes of bronchitis or pneumonia or hemoptysis (more than blood-streaked sputum), or respiratory failure as referred to in paragraph B of 3.03, 3.04, and 3.07, are defined as prolonged symptomatic episodes lasting one or more days and requiring intensive treatment, such as intravenous bronchodilator or antibiotic administration or prolonged inhalational bronchodilator therapy in a hospital, emergency room or equivalent setting. Hospital admissions are defined as inpatient hospitalizations for longer than 24 hours. The medical evidence must also include information documenting adherence to a prescribed regimen of treatment as well as a description of physical signs. For asthma, the medical evidence should include spirometric results obtained between attacks that document the presence of baseline airflow obstruction.

D. *Cystic fibrosis* is a disorder that affects either the respiratory or digestive body systems or both and is responsible for a wide and variable spectrum of clinical manifestations and complications. Confirmation of the diagnosis is based upon an elevated sweat sodium concentration or chloride concentration accompanied by one or more of the following: the presence of chronic obstructive pulmonary disease, insufficiency of exocrine pancreatic function, meconium ileus, or a positive family history. The quantitative pilocarpine iontophoresis procedure for collection of sweat content must be utilized. Two methods are acceptable: the

"Procedure for the Quantitative Iontophoretic Sweat Test for Cystic Fibrosis" published by the Cystic Fibrosis Foundation and contained in, "A Test for Concentration of Electrolytes in Sweat in Cystic Fibrosis of the Pancreas Utilizing Pilocarpine Iontophoresis," Gibson, I.E., and Cooke, R.E., Pediatrics, Vol. 23:545, 1959; or the "Wescor Macroduct System." To establish the diagnosis of cystic fibrosis, the sweat sodium or chloride content must be analyzed quantitatively using an acceptable laboratory technique. Another diagnostic test is the "CF gene mutation analysis" for homozygosity of the cystic fibrosis gene. The pulmonary manifestations of this disorder should be evaluated under 3.04. The nonpulmonary aspects of cystic fibrosis should be evaluated under the digestive body system (5.00). Because cystic fibrosis may involve the respiratory and digestive body systems, the combined effects of the involvement of these body systems must be considered in case adjudication.

E. *Documentation of pulmonary function testing.* The results of spirometry that are used for adjudication under paragraphs A and B of 3.02 and paragraph A of 3.04 should be expressed in liters (L), body temperature and pressure saturated with water vapor (BTPS). The reported one-second forced expiratory volume (FEV_1) and forced vital capacity (FVC) should represent the largest of at least three satisfactory forced expiratory maneuvers. Two of the satisfactory spirograms should be reproducible for both pre-bronchodilator tests and, if indicated, post-bronchodilator tests. A value is considered reproducible if it does not differ from the largest value by more than 5 percent or 0.1 L, whichever is greater. The highest values of the FEV_1 and FVC, whether from the same or different tracings, should be used to assess the severity of the respiratory impairment. Peak flow should be achieved early in expiration, and the spirogram should have a smooth contour with gradually decreasing flow throughout expiration. The zero time for measurement of the FEV_1 and FVC, if not distinct, should be derived by linear back-extrapolation of peak flow to zero volume. A spirogram is satisfactory for measurement of the FEV_1 if the expiratory volume at the back-extrapolated zero time is less than 5 percent of the FVC or 0.1 L, whichever is greater. The spirogram is satisfactory for measurement of the FVC if maximal expiratory effort continues for at least 6 seconds, or if there is a plateau in the volume-time curve with no detectable change in expired volume (VE) during the last 2 seconds of maximal expiratory effort.

Spirometry should be repeated after administration of an aerosolized bronchodilator under supervision of the testing personnel if the pre-bronchodilator FEV_1 value is less than 70 percent of the predicted normal value. Pulmonary function studies should not be performed unless the clinical status is stable (e.g., the individual is not having an asthmatic attack or suffering from an acute respiratory infection or other acute illness). Wheezing is common in asthma, chronic bronchitis, or chronic obstructive pulmonary disease and does not preclude testing. The effect of the administered bronchodilator in relieving bronchospasm and improving ventilatory function is assessed by spirometry. If a bronchodilator is not administered, the reason should be clearly stated in the report. Pulmonary function studies performed to assess airflow obstruction without testing after bronchodilators cannot be used to assess levels of impairment in the range that prevents any gainful work activity, unless the use of bronchodilators is contraindicated. Post-bronchodilator testing should be performed 10 minutes after bronchodilator administration. The dose and name of the bronchodilator administered should be specified. The values in paragraphs A and B of 3.02 must only be used as criteria for the level of ventilatory impairment that exists during the individual's most stable state of health (i.e., any period in time except during or shortly after an exacerbation).

The appropriately labeled spirometric tracing, showing the claimant's name, date of testing, distance per second on the abscissa and the distance per liter (L) on the ordinate, must be incorporated into the file. The manufacturer and model number of the device used to measure and

record the spirogram should be stated. The testing device must accurately measure both time and volume, the latter to within 1 percent of a 3 L calibrating volume. If the spirogram was generated by any means other than direct pen linkage to a mechanical displacement-type spirometer, the testing device must have had a recorded calibration performed previously on the day of the spirometric measurement.

If the spirometer directly measures flow, and volume is derived by electronic integration, the linearity of the device must be documented by recording volume calibrations at three different flow rates of approximately 30 L/min 3 L/6 sec) 60 L/min 3 L/3 sec), and 180 L/min 3 L/sec). The volume calibrations should agree to within 1 percent of a 3 L calibrating volume. The proximity of the flow sensor to the individual should be noted, and it should be stated whether or not a BTPS correction factor was used for the calibration recordings and for the individual's actual spirograms.

The spirogram must be recorded at a speed of at least 20 mm/sec, and the recording device must provide a volume excursion of at least 10 mm/L. If reproductions of the original spirometric tracings are submitted, they must be legible and have a time scale of at least 20 mm/sec and a volume scale of at least 10 mm/L to permit independent measurements. Calculation of FEV_1 from a flow-volume tracing is not acceptable; i.e., the spirogram and calibrations must be presented in a volume-time format at a speed of at least 20 mm/sec and a volume excursion of at least 10 mm/L to permit independent evaluation.

A statement should be made in the pulmonary function test report of the individual's ability to understand directions as well as his or her effort and cooperation in performing the pulmonary function tests.

The pulmonary function tables in 3.02 and 3.04 are based on measurement of standing height without shoes. If an individual has marked spinal deformities (e.g., kyphoscoliosis), the measured span between the fingertips with the upper extremities abducted 90 degrees should be substituted for height when this measurement is greater than the standing height without shoes.

F. *Documentation of chronic impairment of gas exchange.*

1. *Diffusing capacity of the lungs for carbon monoxide (DLCO).* A diffusing capacity of the lungs for carbon monoxide study should be purchased in cases in which there is documentation of chronic pulmonary disease, but the existing evidence, including properly performed spirometry, is not adequate to establish the level of functional impairment. Before purchasing DLCO measurements, the medical history, physical examination, reports of chest x-ray or other appropriate imaging techniques, and spirometric test results must be obtained and reviewed because favorable decisions can often be made based on available evidence without the need for DLCO studies. Purchase of a DLCO study may be appropriate when there is a question of whether an impairment meets or is equivalent in severity to a listing, and the claim cannot otherwise be favorably decided.

The DLCO should be measured by the single breath technique with the individual relaxed and seated. At sea level, the inspired gas mixture should contain approximately 0.3 percent carbon monoxide (CO), 10 percent helium (He), 21 percent oxygen (O_2), and the balance, nitrogen. At altitudes above sea level, the inspired O_2 concentration may be raised to provide an inspired O_2 tension of approximately 150 mm Hg. Alternatively, the sea level mixture may be employed at altitude and the measured DLCO corrected for ambient barometric pressure. Helium may be replaced by another inert gas at an appropriate concentration. The inspired volume (VI) during

the DLCO maneuver should be at least 90 percent of the previously determined vital capacity (VC). The inspiratory time for the VI should be less than 2 seconds, and the breath-hold time should be between 9 and 11 seconds. The washout volume should be between 0.75 and 1.00 L, unless the VC is less than 2 L. In this case, the washout volume may be reduced to 0.50 L; any such change should be noted in the report. The alveolar sample volume should be between 0.5 and 1.0 L and be collected in less than 3 seconds. At least 4 minutes should be allowed for gas washout between repeat studies.

A DLCO should be reported in units of ml CO, standard temperature, pressure, dry (STPD)/min/mm Hg uncorrected for hemoglobin concentration and be based on a single-breath alveolar volume determination. Abnormal hemoglobin or hematocrit values, and/or carboxyhemoglobin levels should be reported along with diffusing capacity.

The DLCO value used for adjudication should represent the mean of at least two acceptable measurements, as defined above. In addition, two acceptable tests should be within 10 percent of each other or 3 ml CO(STPD)min/mm Hg, whichever is larger. The percent difference should be calculated as 100 x (test 1 - test 2)/average DLCO.

The ability of the individual to follow directions and perform the test properly should be described in the written report. The report should include tracings of the VI, breath-hold maneuver, and VE appropriately labeled with the name of the individual and the date of the test. The time axis should be at least 20 mm/sec and the volume axis at least 10 mm/L. The percentage concentrations of inspired O_2, and inspired and expired CO and He for each of the maneuvers should be provided. Sufficient data must be provided, including documentation of the source of the predicted equation, to permit verification that the test was performed adequately, and that, if necessary, corrections for anemia or carboxyhemoglobin were made appropriately.

2. *Arterial blood gas studies (ABGS).* An ABGS performed at rest (while breathing room air, awake and sitting or standing) or during exercise should be analyzed in a laboratory certified by a State or Federal agency. If the laboratory is not certified, it must submit evidence of participation in a national proficiency testing program as well as acceptable quality control at the time of testing. The report should include the altitude of the facility and the barometric pressure on the date of analysis.

Purchase of resting ABGS may be appropriate when there is a question of whether an impairment meets or is equivalent in severity to a listing, and the claim cannot otherwise be favorably decided. If the results of a DLCO study are greater than 40 percent of predicted normal but less than 60 percent of predicted normal, purchase of resting ABGS should be considered. Before purchasing resting ABGS, a program physician, preferably one experienced in the care of patients with pulmonary disease, must review all clinical and laboratory data short of this procedure, including spirometry, to determine whether obtaining the test would present a significant risk to the individual.

3. *Exercise testing.* Exercise testing with measurement of arterial blood gases during exercise may be appropriate in cases in which there is documentation of chronic pulmonary disease, but full development, short of exercise testing, is not adequate to establish if the impairment meets or is equivalent in severity to a listing, and the claim cannot otherwise be favorably decided. In this context, "full development" means that results from spirometry and measurement of DLCO and resting ABGS have been obtained from treating sources or through purchase. Exercise arterial blood gas measurements will be required infrequently and should be purchased only after careful review of the medical history, physical examination, chest x-ray or other appropriate imaging

techniques, spirometry, DLCO, electrocardiogram (ECG), hernatocrit or hemoglobin, and resting blood gas results by a program physician, preferably one experienced in the care of patients with pulmonary disease, to determine whether obtaining the test would present a significant risk to the individual. Oximetry and capillary blood gas analysis are not acceptable substitutes for the measurement of arterial blood gases. Arterial blood gas samples obtained after the completion of exercise are not acceptable for establishing an individual's functional capacity.

Generally, individuals with a DLCO greater than 60 percent of predicted normal would not be considered for exercise testing with measurement of blood gas studies. The exercise test facility must be provided with the claimant's clinical records, reports of chest x-ray or other appropriate imaging techniques, and any spirometry, DLCO, and resting blood gas results obtained as evidence of record. The testing facility must determine whether exercise testing presents a significant risk to the individual; if it does, the reason for not performing the test must be reported in writing.

4. *Methodology.* Individuals considered for exercise testing first should have resting arterial blood partial pressure of oxygen ($P0_2$), resting arterial blood partial pressure of carbon dioxide ($PC0_2$) and negative log of hydrogen ion concentration (pH) determinations by the testing facility. The sample should be obtained in either the sitting or standing position. The individual should then perform exercise under steady state conditions, preferably on treadmill, breathing room air, for a period of 4 to 6 minutes at a speed and grade providing an Oxygen consumption of approximately 17.5 ml/kg/ min (5 METs). If a bicycle ergometer is used, an exercise equivalent of 5 METs (e.g., 450 kpm/min, or 75 watts for a 176 pound (80 kilogram) person) should be used. If the individual is able to complete this level of exercise without achieving listing-level hypoxemia, then he or she should be exercised at higher workloads to determine exercise capacity. A warm-up period of treadmill walking or cycling may be performed to acquaint the individual with the exercise procedure. If during the warm-up period the individual cannot achieve an exercise level of 5 METs, a lower workload may be selected in keeping with the estimate of exercise capacity. The individual should be monitored by ECG throughout the exercise and in the immediate post-exercise period. Blood pressure and an ECG should be recorded during each minute of exercise. During the final 2 minutes of a specific level of steady state exercise, an arterial blood sample should be drawn and analyzed for oxygen pressure (or tension) (PO_2), carbon dioxide pressure (or tension) (PCO_2), and pH. At the discretion of the testing facility, the sample may be obtained either from an indwelling arterial catheter or by direct arterial puncture. If possible, in order to evaluate exercise capacity more accurately, a test site should be selected that has the capability to measure minute ventilation, O_2 consumption, and carbon dioxide (CO_2) production. If the claimant fails to complete 4 to 6 minutes of steady state exercise, the testing laboratory should comment on the reason and report the actual duration and levels of exercise performed. This comment is necessary to determine if the individual 's test performance was limited by lack of effort or other impairment (e.g., cardiac, peripheral vascular, musculoskeletal, neurological).

The exercise test report should contain representative ECG strips taken before, during and after exercise; resting and exercise arterial blood gas values; treadmill speed and grade settings, or, if a bicycle ergometer was used, exercise levels expressed in watts or kpm/min; and the duration of exercise. Body weight also should be recorded. If measured, O_2 consumption (STPD), minute ventilation (BTPS), and CO_2 production (STPD) also should be reported. The altitude of the test site, its normal range of blood gas values, and the barometric pressure on the test date must be noted.

G. *Chronic cor pulmonale and pulmonary vascular disease.* The establishment of an impairment attributable to irreversible cor pulmonale secondary to chronic pulmonary hypertension requires documentation by signs and laboratory findings of right ventricular overload or failure (e.g., an early diastolic right-sided gallop on auscultation, neck vein distension, hepatomegaly, peripheral edema, right ventricular outflow tract enlargement on x-ray or other appropriate imaging techniques, right ventricular hypertrophy on ECG, and increased pulmonary artery pressure measured by right heart catheterization available from treating sources). Cardiac catheterization will not be purchased. Because hypoxemia may accompany heart failure and is also a cause of pulmonary hypertension, and may be associated with hypoventilation and respiratory acidosis, arterial blood gases may demonstrate hypoxemia (decreased PO_2), CO_2 retention (increased PCO_2), and acidosis (decreased pH). Polycythemia with an elevated red blood cell count and hernatocrit may be found in the presence of chronic hypoxemia.

P-pulmonale on the ECG does not establish chronic pulmonary hypertension or chronic cor pulmonale. Evidence of florid right heart failure need not be present at the time of adjudication for a listing (e.g., 3.09) to be satisfied, but the medical evidence of record should establish that cor pulmonale is chronic and irreversible.

H. *Sleep-related breathing disorders.* Sleep-related breathing disorders (sleep apneas) are caused by periodic cessation of respiration associated with hypoxemia and frequent arousals from sleep. Although many individuals with one of these disorders will respond to prescribed treatment, in some, the disturbed sleep pattern and associated chronic nocturnal hypoxemia cause daytime sleepiness with chronic pulmonary hypertension and/or disturbances in cognitive function. Because daytime sleepiness can affect memory, orientation and personality, a longitudinal treatment record may be needed to evaluate mental functioning. Not all individuals with sleep apnea develop a functional impairment that affects work activity. When any gainful work is precluded, the physiologic basis for the impairment may be chronic cor pulmonale. Chronic hypoxemia due to episodic apnea may cause pulmonary hypertension (see 3.00G and 3.09). Daytime somnolence may be associated with disturbance in cognitive vigilance. Impairment of cognitive function may be evaluated under organic mental disorders (12.02).

I. *Effects of obesity.* Obesity is a medically determinable impairment that is often associated with disturbance of the respiratory system, and disturbance of this system can be a major cause of disability in individuals with obesity. The combined effects of obesity with respiratory impairments can be greater than the effects of each of the impairments considered separately. Therefore, when determining whether an individual with obesity has a listing-level impairment or combination of impairments, and when assessing a claim at other steps of the sequential evaluation process, including when assessing an individual's residual functional capacity, adjudicators must consider any additional and cumulative effects of obesity.

3.01 Category of Impairments, Respiratory System

3.02 ***Chronic Pulmonary insufficiency***

A. Chronic obstructive pulmonary disease due to any cause, with the FEV_1 equal to or less than the values specified in table I corresponding to the person's height without shoes. (In cases of marked spinal deformity, see 3.00E.);

Table II

Height without Shoes (centimeters)	Height without Shoes (inches)	FVC Equal to or less than (L,BTPS)
154 or less	60 or less	1.25
155-160	61-63	1.35
161-165	64-65	1.45
166-170	66-67	1.55
171-175	68-69	1.65
176-180	70-71	1.75
181 or more	72 or more	1.85

Or

C. *Chronic impairment of gas exchange due to clinically documented pulmonary disease.* With:

1. Single breath DLCO (see 3.00Fl) less than 10.5 ml/min/mrn Hg or less than 40 percent of the predicted normal value. (Predicted values must either be based on data obtained at the test site or published values from a laboratory using the same technique as the test site. The source of the predicted values should be reported. If they are not published, they should be submitted in the form of a table or nomogram); or

2. Arterial blood gas values of PO_2 and simultaneously determined PCO_2 measured while at rest (breathing room air, awake and sitting or standing) in a clinically stable condition on at least two occasions, three or more weeks apart within a 6-month period, equal to or, less then the values specified in the applicable table III-A or III-B or III-C:

Table III-A

(Applicable at test sites less than 3,000 feet above sea level)

Arterial PCO_2 (mm Hg) and	Arterial PO_2 Equal to or Less than (mm Hg)
30 or below	65
31	64
32	63
33	62
34	61
35	60
36	59
37	58
38	57
39	56
40 or above	55

Table III-B

(Applicable at test sites 3,000 through 6,000 feet above sea level)

Arterial PCO_2 (mm Hg) and	Arterial PO_2 Equal to or Less than (mm Hg)
30 or below	60
31	59
32	58
33	57
34	56
35	55
36	54
37	53
38	52
39	51
40 or above	50

Table III-C

(Applicable at test sites over 6,000 feet above sea level)

Arterial PCO_2 (mm Hg) and	Arterial PO_2 equal to or less than (mm Hg)
30 or below	55
31	54
32	53
33	52
34	51
35	50
36	49
37	48
38	47
39	46
40 or above	45

Or

3. Arterial blood gas values of PO_2 and simultaneously determined PCO_2 during steady state exercise breathing room air (level of exercise equivalent to or less than 17.5 ml O_2 consumption/kg/min or 5 METs) equal to or less than the values specified in the applicable table III-A or III-B or III-C in 3.02 C2.

3.03 ***Asthma.*** With:

A. Chronic asthmatic bronchitis. Evaluate under the criteria for chronic obstructive pulmonary disease in 3.02A;

Or

B. Attacks (as defined in 3.00C), in spite of prescribed treatment and requiring physician intervention, occurring at least once every 2 months or at least six times a year. Each in-patient hospitalization for longer than 24 hours for control of asthma counts as two attacks, and an evaluation period of at least 12 consecutive months must be used to determine the frequency of attacks.

3.04 ***Cystic fibrosis***. With:

A. An FEV_1 equal to or less than the appropriate value specified in table IV corresponding to the individual's height without shoes. (In cases of marked spinal deformity, see. 3.00E.);

Or

B. Episodes of bronchitis or pneumonia or hemoptysis (more than bloodstreaked sputum) or respiratory failure (documented according to 3.00C, requiring physician intervention, occurring at least once every 2 months or at least six times a year. Each inpatient hospitalization for longer than 24 hours for treatment counts as two episodes, and an evaluation period of at least 12 consecutive months must be used to determine the frequency of episodes;

Or

C. Persistent pulmonary infection accompanied by superimposed, recurrent, symptomatic episodes of increased bacterial infection occurring at least once every 6 months and requiring intravenous or nebulization antimicrobial therapy.

Table IV
(Applicable only for evaluation under 3.04A - cystic fibrosis)

Height without Shoes (centimeters)	Height without Shoes(inches)	FEV_1 Equal to or less than (L,BTPS)
154 or less	60 or less	1.45
155-159	61-62	1.55
160-164	63-64	1.65
165-169	65-66	1.75
170-174	67-68	1.85
175-179	69-70	1.95
180 or more	71 or more	2.05

3.05 (Reserved)

3.06 ***Pneumoconiosis*** (demonstrated by appropriate imaging techniques). Evaluate under the appropriate criteria in 3.02.

3.07 ***Bronchiectasis*** (demonstrated by appropriate imaging techniques). With:

A. Impairment of pulmonary function due to extensive disease. Evaluate under the appropriate criteria in 3.02;

Or

B. Episodes of bronchitis or pneumonia or hemoptysis (more than bloodstreaked sputum) or respiratory failure (documented according to 3.00C), requiring physician intervention, occurring at least once every 2 months or at least six times a year. Each inpatient hospitalization for longer than 24 hours for treatment counts as two episodes, and an evaluation of at least 12 consecutive months must be used to determine the frequency of episodes.

3.08 ***Mycobacterial, mycotic, and other chronic persistent infections of the lung*** (see 3.00B). Evaluate under the appropriate criteria in 3.02.

3.09 ***Cor pulmonale secondary to chronic pulmonary vascular hypertension***. Clinical evidence of cor pulmonale (documented according to 3.00G) with:

A. Mean pulmonary artery pressure greater than 40 mm Hg;

Or

B. Arterial hypoxemia. Evaluate under the criteria in 3.02C2;

Or

C. Evaluate under the applicable criteria in 4.02.

3.10 ***Sleep-related breathing disorders***. Evaluate under 3.09 (chronic cor pulmonale), or 12.02 (organic mental disorders).

3.11 ***Lung Transplant.*** Consider under a disability for 12 months following the date of surgery; thereafter, evaluate the residual impairment.

4.00 Cardiovascular System

A. *Introduction.* The listings in this section describe impairments resulting from cardiovascular disease based on symptoms, physical signs, laboratory test abnormalities, and response to a regimen of therapy prescribed by a treating source. *A* longitudinal clinical record covering a period of not less than 3 months of observations and therapy is usually necessary for the assessment of severity and expected duration of cardiovascular impairment, unless the claim can be decided favorably on the basis of the current evidence. All relevant evidence must be considered in assessing disability.

Many individuals, especially those who have listing-level impairments, will have received the benefit of medically prescribed treatment. Whenever there is evidence of such treatment, the longitudinal clinical record must include a description of the therapy prescribed by the treating source and response, in addition to information about the nature and severity of the impairment. It is important to document any prescribed therapy and response because this medical management may have improved the individual's functional status. The longitudinal record should provide information regarding functional recovery, if any.

Some individuals will not have received ongoing treatment or have an ongoing relationship with the medical community despite the existence of a severe impairment(s). Unless the claim can be decided favorably on the basis of the current evidence, a longitudinal record is still important because it will provide information about such things as the ongoing medical severity of the impairment, the degree of recovery from cardiac insult, the level of the individual's functioning, and the frequency, severity, and duration of symptoms. Also, several listings include a requirement for continuing signs and symptoms despite a regimen of prescribed treatment. Even though an individual who does not receive treatment may not be able to show an impairment that meets the criteria of these listings, the individual may have an impairment(s) equivalent in severity to one of the listed impairments or be disabled because of a limited residual functional capacity.

Indeed, it must be remembered that these listings are only examples of common cardiovascular disorders that are severe enough to prevent a person from engaging in gainful activity. Therefore, in any case in which you have a medically determinable impairment that is not listed, or a combination of impairments no one of which meets a listing, we will consider a medical equivalence determination. Individuals who have an impairment(s) with a level of severity which does not meet or equal the criteria of the cardiovascular listings may or may not have the residual functional capacity (RFC) which would enable them to engage in substantial gainful activity. Evaluation of the impairment(s) of these individuals should proceed through the final steps of the sequential evaluation process (or, as appropriate, the steps in the medical improvement review standard).

B. *Cardiovascular impairment* results from one or more of four consequences of heart disease:

1. Chronic heart failure or ventricular dysfunction.

2. Discomfort or pain due to myocardial ischemia, with or without necrosis of heart muscle.

3. Syncope, or near syncope, due to inadequate cerebral perfusion from any cardiac cause such as obstruction of flow or disturbance in rhythm or conduction resulting in inadequate cardiac output.

4. Central cyanosis due to right-to-left shunt, arterial desaturation, or pulmonary vascular disease.

Impairment from diseases of arteries and veins may result from disorders of the vasculature in the central nervous system (I 1.04A, B), eyes (2.02-2.04), kidney (6.02), and other organs.

C. *Documentation.* Each individual's file must include sufficiently detailed reports on history, physical examinations, laboratory studies, and any prescribed therapy and response to allow an independent reviewer to assess the severity and duration of the cardiovascular impairment.

1. Electrocardiography.

a. An original or legible copy of the 12-lead electrocardiogram (ECG) obtained at rest must be submitted, appropriately dated and labeled, with the standardization inscribed on the tracing. Alteration in standardization of specific leads (such as to accommodate large QRS amplitudes) must be identified on those leads.

(1) Detailed descriptions or computer--averaged signals without original or legible copies of the ECG as described in subsection 4.00C1a are not acceptable.

(2) The effects of drugs or electrolyte abnormalities must be considered as possible noncoronary causes of ECG abnormalities of ventricular repolarization; i.e., those involving the ST segment and T wave. If available, the predrug (especially digitalis glycoside) ECG should be submitted.

(3) The term "ischemic" is used in 4.04A to describe an abnormal ST segment deviation. Nonspecific repolarization abnormalities should not be confused with "ischemic" changes.

b. ECGs obtained in conjunction with treadmill, bicycle, or arm exercise tests should meet the following specifications:

(1) ECGs must include the original calibrated ECG tracings or a legible copy.

(2) A 12-lead baseline ECG must be recorded in the upright position before exercise.

(3) A 12-lead ECG should be recorded at the end of each minute of exercise, including at the time the ST segment abnormalities reach or exceed the criteria for abnormality described in 4.04A or the individual experiences chest discomfort or other abnormalities, and also when the exercise test is terminated.

(4) If ECG documentation of the effects of hyperventilation is obtained, the exercise test should be deferred for at least 10 minutes because metabolic changes of hyperventilation may alter the physiologic and ECG response to exercise.

(5) Post-exercise ECGs should be recorded using a generally accepted protocol consistent with the prevailing state of medical knowledge and clinical practice.

(6) All resting, exercise, and recovery ECG strips must have a standardization inscribed on the tracing. The ECG strips should be labeled to indicate the times recorded and the relationship to the stage of the exercise protocol. The speed and grade (treadmill test) or work rate (bicycle or arm ergometric test) should be recorded. The highest level of exercise achieved, blood pressure levels during testing, and the reason(s) for terminating the test (including limiting signs or symptoms) must be recorded.

2. Purchasing exercise tests.

a. It is well recognized by medical experts that exercise testing is the best tool currently available for estimating maximal aerobic capacity in individuals with cardiovascular impairments. Purchase of an exercise test may be appropriate when there is a question whether an impairment meets or is equivalent in severity to one of the listings, or when there is insufficient evidence in the record to evaluate aerobic capacity, and the claim cannot otherwise be favorably decided. Before purchasing an exercise test, a program physician, preferably one with experience in the care of patients with cardiovascular disease, must review the pertinent history, physical examinations, and laboratory tests to determine whether obtaining the test would present a significant risk to the individual (see 4.00C2c). Purchase may be indicated when there is no significant risk to exercise testing and there is no timely test of record. An exercise test is generally considered timely for 12 months after the date performed, provided there has been no change in clinical status that may alter the severity of the cardiac impairment.

b. Methodology.

(1) When an exercise test is purchased it should be a "sign- or symptom-limited" test characterized by a progressive multistage regimen. A purchased exercise test must be performed using a generally accepted protocol consistent with the prevailing state of medical knowledge and clinical practice. A description of the protocol that was followed must be provided and the test must meet the requirements of 4.00CIb and this section. A pre-exercise posthyperventilation tracing may be essential for the proper evaluation of an "abnormal" test in certain circumstances, such as in women with evidence of mitral valve prolapse.

(2) The exercise test should be paced to the capabilities of the individual and be supervised by a physician. With a treadmill test, the speed, grade (incline) and duration of exercise must be recorded for each exercise test stage performed. Other exercise test protocols or techniques that are used should utilize similar workloads.

(3) Levels of exercise should be described in terms of workload and duration of each stage; e.g., treadmill speed and grade, or bicycle ergometer work rate in kpm/min or watts.

(4) Normally, systolic blood pressure and heart rate increase gradually with exercise. A decrease in systolic blood pressure during exercise below the usual resting level is often associated with ischemia-induced left ventricular dysfunction resulting in decreased cardiac output. Some individuals (because of deconditioning or apprehension) with increased sympathetic responses may increase their systolic blood pressure and heart rate above their usual resting level just before and early into exercise. This occurrence may limit the ability to assess the significance of an early decrease in systolic blood pressure and heart rate if exercise is discontinued shortly after initiation. In addition, isolated systolic hypertension may be a manifestation of arteriosclerosis.

(5) The exercise laboratory's physical environment, staffing, and equipment should meet the generally accepted standards for adult exercise test laboratories.

c. Risk factors in exercise testing.

The following are examples of situations in which exercise testing will not be purchased: unstable progressive angina pectoris, a history of acute myocardial infarction within the past 3 months, New York Heart Association (NYHA) class IV heart failure, cardiac drug toxicity, uncontrolled serious arrhythmia (including uncontrolled atrial fibrillation, Mobitz II, and third-degree block), Wolff-Parkinson-White syndrome, uncontrolled severe systemic arterial hypertension, marked pulmonary hypertension, unrepaired aortic dissection, left main stenosis of 50 percent or greater, marked aortic stenosis, chronic or dissecting aortic aneurysm, recent pulmonary embolism, hypertrophic cardiomyopathy, limiting neurological or musculoskeletal impairments, or an acute illness. In addition, an exercise test should not be purchased for individuals for whom the performance of the test is considered to constitute a significant risk by a program physician, preferably one experienced in the care of patients with cardiovascular disease, even in the absence of any of the above risk factors. In defining risk, the program physician, in accordance with the regulations and other instructions on consultative examinations, will generally give great weight to the treating physicians' opinions and will generally not override them. In the rare situation in which the program physician does override the treating source's opinion, a written rationale must be prepared documenting the reasons for overriding the opinion.

d. In order to permit maximal, attainable restoration of functional capacity, exercise testing should not be purchased until 3 months after an acute myocardial infarction, surgical myocardial revascularization, or other open-heart surgical procedures. Purchase of an exercise test should also be deferred for 3 months after percutaneous transluminal coronary angioplasty because restenosis with ischernic symptoms may occur within a few months of angioplasty (see 4.001)). Also, individuals who have had a period of bedrest or inactivity (e.g., 2 weeks) that results in a reversible deconditioned state may do poorly if exercise testing is performed at that time.

e. Evaluation.

(1) Exercise testing is evaluated on the basis of the work level at which the test becomes abnormal, as documented by onset of signs or symptoms and any ECG abnormalities listed in 4.04A. The ability or inability to complete an exercise test is not, by itself, evidence that a person is free from ischemic heart disease. The results of an exercise test must be considered in the context of all of the other evidence in the individual's case record. If the individual is under the care of a treating physician for a cardiac impairment, and this physician has not performed an exercise test and there are no reported significant risks to testing (see 4.00C2c), a statement should be requested from the treating physician explaining why it was not done or should not be done before deciding whether an exercise test should be purchased. In those rare situations in which the treating source's opinion is overridden, follow 4.00C2c. If there is no treating physician, the program physician will be responsible for assessing the risk to exercise testing.

(2) Limitations to exercise test interpretation include the presence of noncoronary or nonischernic factors that may influence the hemodynamic and ECG response to exercise. such as hypokalemia or other electrolyte abnormality, hyperventilation, vasoregulatory deconditioning, prolonged periods of physical inactivity (e.g., 2 weeks of bedrest), significant anemia, left bundle branch block pattern on the ECG (and other conduction abnormalities that do not preclude the purchase of exercise testing), and other heart diseases or abnormalities (particularly va1vular heart disease). Digitalis glycosides may cause ST segment abnormalities at rest, during, and after exercise. Digitalis or other drug-related ST segment displacement, present at rest, may become accentuated with exercise and make ECG interpretation difficult, but such drugs do not invalidate an otherwise normal exercise test. Diuretic-induced hypokalemia and left ventricular hypertrophy may also be associated with repolarization changes and behave similarly. Finally, treatment with beta-blockers slows the heart rate more at near maximal exertion than at rest; this limits apparent chronotropic capacity.

3. Other studies.

Information from two-dimensional and Doppler echocardiographic studies of ventricular size and function as well as radionuclide (thallium201) myocardial "perfusion" or radionuclide (technetium 99m) ventriculograms (RVG or MUGA) may be useful. These techniques can provide a reliable estimate of ejection fraction. In selected cases, these tests may be purchased after a medical history and physical examination, report of appropriate medically acceptable imaging, ECGs, and other appropriate tests have been evaluated, preferably by a program physician with experience in the care of patients with cardiovascular disease. Medically acceptable imaging includes, but is not limited to, x-ray imaging, computerized axial tomography (CAT scan) or magnetic resonance imaging (MRI), with or without contrast material, myelography, and radionuclear bone scans. “Appropriate” means that the technique used is the proper one to support the evaluation and diagnosis of the impairment. Purchase should be

considered when other information available is not adequate to assess whether the individual may have severe ventricular dysfunction or myocardial ischemia and there is no significant risk involved (follow 4.00C2a guides), and the claim cannot be favorably decided on any other basis.

Exercise testing, with measurement of maximal oxygen uptake (VO_2) provides an accurate determination of aerobic capacity. An exercise test without measurement of oxygen uptake provides an estimate of aerobic capacity. When the results of tests with measurement of oxygen uptake are available, every reasonable effort should be made to obtain them.

The recording of properly calibrated ambulatory ECGs for analysis of ST segment signals with a concomitantly recorded symptom and treatment log may permit more adequate evaluation of chest discomfort during activities of daily living, but the significance of these data for disability evaluation has not been established in the absence of symptoms (e.g., silent ischemia). This information (including selected segments of both the ECG recording and summary report of the patient diary) may be submitted for the record.

4. **Cardiac catheterization** will not be purchased by the Social Security Administration.

a. Coronary arteriography.

If results of such testing are available, the report should be obtained and considered as to the quality and type of data provided and its relevance to the evaluation of the impairment. A copy of the report of the cardiac catheterization and ancillary studies should also be obtained. The report should provide information citing the method of assessing coronary arterial lumen diameter and the nature and location of obstructive lesions. Drug treatment at baseline and during the procedure should be reported. Coronary artery spasm induced by intracoronary catheterization is not to be considered evidence of ischemic disease. Some individuals with significant coronary atherosclerotic obstruction have collateral vessels that supply the myocardium distal to the arterial obstruction so that there is no evidence of myocardial damage or ischemia, even with exercise. When available, quantitative computer measurements and analyses should be considered in the interpretation of severity of stenotic lesions.

b. Left ventriculography (by angiography).

The report should describe the wall motion of the myocardium with regard to any areas of hypokinesis, akinesis, or dyskinesis, and the overall contraction of the ventricle as measured by the ejection fraction. Measurement of chamber volumes and pressures may be useful. When available, quantitative computer analysis provides precise measurement of segmental left ventricular wall thickness and motion. There is often a poor correlation between left ventricular function at rest and functional capacity for physical activity.

D. Treatment and relationship to functional status.

1. In general, conclusions about the severity of a cardiovascular impairment cannot be made on the basis of type of treatment rendered or anticipated. The overall clinical and laboratory evidence, including the treatment plan(s) or results, should be persuasive that a listing-level impairment exists. The amount of function restored and the time required for improvement after treatment (medical, surgical, or a prescribed program of progressive physical activity) vary with the nature and extent of the disorder, the type of treatment, and other factors. Depending upon the timing of this treatment in relation to the alleged onset date of disability, impairment evaluation may need

to be deferred for a period of up to 3 months from the date of treatment to permit consideration of treatment effects. Evaluation should not be deferred if the claim can be favorably decided based upon the available evidence.

2. The usual time after myocardial infarction, valvular and/or revascularization surgery for adequate assessment of the results of treatment is considered to be 3 months. If an exercise test is performed by a treating source within a week or two after angioplasty, and there is no significant change in clinical status during the 3-month period after the angioplasty that would invalidate the implications of the exercise test results, the exercise test results may be used to reflect functional capacity during the period in question. However, if the test was done immediately following an acute myocardial infarction or during a period of protracted inactivity, the results should not be projected to 3 months even if there is no change in clinical status.

3. An individual who has undergone cardiac transplantation will be considered under a disability for I year following the surgery because, during the first year, there is a greater likelihood of rejection of the organ and recurrent infection. After the first year post transplantation, continuing disability evaluation will be based upon residual impairment as shown by symptoms, signs, and laboratory findings. Absence of symptoms, signs, and laboratory findings indicative of cardiac dysfunction will be included in the consideration of whether medical improvement (as defined in §§ 404.1579(b)(1) and (c)(1), 404.1594 (b)(1) and (c)(1), or 416.994 (b)(1)(i) and (b)(2)(i), as appropriate) has occurred.

E. Clinical syndromes.

1. Chronic heart failure (ventricular dysfunction) is considered in these listings as one category whatever its etiology, i.e., atherosclerotic, hypertensive, rheumatic, pulmonary, congenital or other organic heart disease. Chronic heart failure may manifest itself by:

a. Pulmonary or systemic congestion, or both; or

b. Symptoms of limited cardiac output, such as weakness, fatigue, or intolerance of physical activity.

For the purpose of 4.02A, pulmonary and systemic congestion are not considered to have been established unless there is or has been evidence of fluid retention, such as hepatomegaly or ascites, or peripheral or pulmonary edema of cardiac origin. The findings of fluid retention need not be present at the time of adjudication because congestion may be controlled with medication. Chronic heart failure due to limited cardiac output is not considered to have been established for the purpose of 4.02B unless symptoms occur with ordinary daily activities; i.e., activity restriction as manifested by a need to decrease activity or pace, or to rest intermittently, and are associated with one or more physical signs or abnormal laboratory studies listed in 4.02B. These studies include exercise testing with ECG and blood pressure recording and/or appropriate imaging techniques, such as two-dimensional echocardiography or radionuclide or contrast ventriculography. The exercise criteria are outlined in 4.02B1. In addition, other abnormal symptoms, signs, or laboratory test results that lend credence to the impression of ventricular dysfunction should be considered.

2. For the purposes of 4.03, hypertensive cardiovascular disease is evaluated by reference to the specific organ system involved (heart, brain, kidneys, or eyes). The presence of organic impairment must be established by appropriate physical signs and laboratory test abnormalities as specified in 4.02 or 4.04, or for the body system involved.

3. Ischemic (coronary) heart disease may result in an impairment due to myocardial ischemia and/or ventricular dysfunction or infarction. For the purposes of 4.04, the clinical determination that discomfort of myocardial ischemic origin (angina pectoris) is present must be supported by objective evidence as described under 4.00C 1, 2, 3, or 4.

a. Discomfort of myocardial ischemic origin (angina pectoris) is discomfort that is precipitated by effort and/or emotion and promptly relieved by sublingual nitroglycerin, other rapidly acting nitrates, or rest. Typically, the discomfort is located in the chest (usually substernal) and described as crushing, squeezing, burning, aching, or oppressive. Sharp, sticking, or cramping discomfort is considered less common or atypical. Discomfort occurring with activity or emotion should be described specifically as to timing and usual inciting factors (type and intensity), character, location, radiation, duration, and response to nitrate therapy or rest.

b. So-called anginal equivalent may be localized to the neck, jaw(s), or hand(s) and has the same precipitating and relieving factors as typical chest discomfort. Isolated shortness of breath (dyspnea) is not considered an anginal equivalent for purposes of adjudication.

c. Variant angina of the Prinzmetal type; i.e., rest angina with transitory ST segment elevation on ECG, may have the same significance as typical angina, described in 4.00E3a.

d. If there is documented evidence of silent ischemia or restricted activity to prevent chest discomfort, this information must be considered along with all available evidence to determine if an equivalence decision is appropriate.

e. Chest discomfort of myocardial ischernic origin is usually caused by coronary artery disease. However, ischemic discomfort may be caused by noncoronary artery conditions, such as critical aortic stenosis, hypertrophic cardiomyopathy, pulmonary hypertension, or anemia. These conditions should be distinguished from coronary artery disease, because the evaluation criteria, management, and prognosis (duration) may differ from that of coronary artery disease.

f. Chest discomfort of nonischemic origin may result from other cardiac conditions such as pericarditis and mitral valve prolapse. Noncardiac conditions may also produce symptoms mimicking that of myocardial ischemia. These conditions include gastrointestinal tract disorders, such as esophageal spasm, esophagitis, hiatal hernia, biliary tract disease, gastritis, peptic ulcer, and pancreatitis, and musculoskeletal syndromes, such as chest wall muscle spasm, chest wall syndrome (especially after coronary bypass surgery), costochondritis, and cervical or dorsal arthritis. Hyperventilation may also mimic ischemic discomfort. Such disorders should be considered before concluding that chest discomfort is of myocardial ischemic origin.

4. Peripheral arterial disease.

The level of impairment is based on the symptomatology, physical findings, Doppler studies before and after a standard exercise test, or angiographic findings.

The requirements for evaluating peripheral arterial disease in 4.12B are based on the ratio of the systolic blood pressure at the ankle to the systolic blood pressure at the brachial artery, determined in the supine position at the same time. Techniques for obtaining ankle systolic blood pressures include Doppler, plethysmographic studies, or other techniques.

Listing 4.12B1 is met when the resting ankle/brachial systolic blood pressure ratio is less than 0.50. Listing 4.12B2 provides additional criteria for evaluating peripheral arterial impairment on the basis of exercise studies when the resting ankle/brachial systolic blood pressure ratio is 0.50 or above. The decision to obtain exercise studies should be based on an evaluation of the existing clinical evidence, but exercise studies are rarely warranted when the resting ankle/brachial systolic blood pressure ratio is 0.80 or above. The results of exercise studies should describe the level of exercise, e.g., speed and grade of the treadmill settings, the duration of exercise, symptoms during exercise, the reasons for stopping exercise if the expected level of exercise was not attained, blood pressures at the ankle and other pertinent sites measured after exercise, and the time required to return the systolic blood pressure toward or to the pre-exercise level. When an exercise Doppler study is purchased by the Social Security Administration, the requested exercise must be on a treadmill at 2 mph on a 10 or 12 percent grade for 5 minutes. Exercise studies should not be performed on individuals for whom exercise poses a significant risk.

Application of the criteria in 4.12B may be limited in individuals who have marked calcific (Monckeberg's) sclerosis of the peripheral arteries or marked small vessel disease associated with diabetes mellitus.

F. *Effects of obesity.* Obesity is a medically determinable impairment that is often associated with disturbance of the cardiovascular system, and disturbance of this system can be a major cause of disability in individuals with obesity. The combined effects of obesity with cardiovascular impairments can be greater than the effects of each of the impairments considered separately. Therefore, when determining whether an individual with obesity has a listing-level impairment or combination of impairments, and when assessing a claim at other steps of the sequential evaluation process, including when assessing an individual's residual functional capacity, adjudicators must consider any additional and cumulative effects of obesity.

4.01 Category of Impairments, Cardiovascular System

4.02 ***Chronic heart failure*** while on a regimen of prescribed treatment (see 4.00A if there is no regimen of prescribed treatment). With one of the following:

A. Documented cardiac enlargement by appropriate imaging techniques (e.g., a cardiothoracic ratio of greater than 0.50 on a PA chest x-ray with good inspiratory effort or left ventricular diastolic diameter of greater than 5.5 cm on two-dimensional echocardiography), resulting in inability to carry on any physical activity, and with symptoms of inadequate cardiac output, pulmonary congestion, systemic congestion, or anginal syndrome at rest (e.g., recurrent or persistent fatigue, dyspnea, orthopnea, anginal discomfort);

Or

B. Documented cardiac enlargement by appropriate imaging techniques (see 4.02A) or ventricular dysfunction manifested by S3, abnormal wall motion, or left ventricular ejection fraction of 30 percent or less by appropriate imaging techniques; and

1. Inability to perform on an exercise test at a workload equivalent to 5 METs or less due to symptoms of chronic heart failure, or, in rare instances, a need to stop exercise testing at less than this level of work because of:

a. Three or more consecutive ventricular premature beats or three or more multiform beats; or

b. Failure to increase systolic blood pressure by 10 mmHg, or decrease in systolic pressure below the usual resting level (see 4.00C2b); or

c. Signs attributable to inadequate cerebral perfusion, such as ataxic gait or mental confusion, and

2. Resulting in marked limitation of physical activity, as demonstrated by fatigue, palpitation, dyspnea, or anginal discomfort on ordinary physical activity, even though the individual is comfortable at rest;

Or

C. Cor pulmonale fulfilling the criteria in 4.02A or B.

4.03 ***Hypertensive cardiovascular disease***. Evaluate under 4.02 or 4.04, or under the criteria for the affected body system (2.02 through 2.04, 6.02, or 11.04A or B).

4.04 ***Ischemic heart disease,*** with chest discomfort associated with myocardial ischemia, as described in 4.00E3, while on a regimen of prescribed treatment (see 4.00A if there is no regimen of prescribed treatment). With one of the following:

A. Sign-or-symptom limited exercise test demonstrating at least one of the following manifestations at a workload equivalent to 5 METs or less:

1. Horizontal or downsloping depression, in the absence of digitalis glycoside therapy and/or hypokalemia, of the ST segment of at least -0.10 millivolts (-1.0 mm) in at least 3 consecutive complexes that are on a level baseline in any lead (other than AVR) and that have a typical ischemic time course of development and resolution (progression of horizontal or downsloping ST depression with exercise, and persistence of depression of at least -0.10 millivolts for at least 1 minute of recovery); or

2. An upsloping ST junction depression, in the absence of digitalis glycoside therapy and/or hypokalemia, in any lead (except AVR) of at least -0.2 millivolts or more for at least 0.08 seconds after the J junction and persisting for at least 1 minute of recovery; or

3. At least 0.1 millivolt (1 mm) ST elevation above resting baseline during both exercise and 3 or more minutes of recovery in ECG leads with low R and T waves in the leads demonstrating the ST segment displacement; or

4. Failure to increase systolic pressure by 10 mmHg, or decrease in systolic pressure below usual clinical resting level (see 4.00C2b); or

5. Documented reversible radionuclide "perfusion" (thallium201) defect at an exercise level equivalent to 5 METs or less;

Or

B. Impaired myocardial function, documented by evidence (as outlined under 4.00C3 or 4.00C4b) of hypokinetic, akinetic, or dyskinetic myocardial free wall or septal wall motion with left ventricular ejection fraction of 30 percent or less, and an evaluating program physician, preferably one experienced in the care of patients with cardiovascular disease, has concluded that

performance of exercise testing would present a significant risk to the individual, and resulting in marked limitation of physical activity, as demonstrated by fatigue, palpitation, dyspnea, or anginal discomfort on ordinary physical activity, even though the individual is comfortable at rest;

Or

C. Coronary artery disease, demonstrated by angiography (obtained independent of Social Security disability evaluation), and an evaluating program physician, preferably one experienced in the care of patients with cardiovascular disease, has concluded that performance of exercise testing would present a significant risk to the individual, with both 1 and 2:

1. Angiographic evidence revealing:

a. 50 percent or more narrowing of a nonbypassed left main coronary artery; or

b. 70 percent or more narrowing of another nonbypassed coronary artery; or

c. 50 percent or more narrowing involving a long (greater than 1 cm) segment of a nonbypassed coronary artery; or

d. 50 percent or more narrowing of at least 2 nonbypassed coronary arteries; or

e. Total obstruction of a bypass graft vessel; and

2. Resulting in marked limitation of physical activity, as demonstrated by fatigue, palpitation, dyspnea, or anginal discomfort on ordinary physical activity, even though the individual is comfortable at rest.

4.05 ***Recurrent arrhythmias,*** not related to reversible causes such as electrolyte abnormalities or digitalis glycoside or antiarrhythmic drug toxicity, resulting in uncontrolled repeated episodes of cardiac syncope or near syncope and arrhythmia despite prescribed treatment (see 4.00A if there is no prescribed treatment), documented by resting or ambulatory (Holter) electrocardiography coincident with the occurrence of syncope or near syncope.

4.06 ***Symptomatic congenital heart disease*** (cyanotic or acyanotic), documented by appropriate imaging techniques (as outlined under 4.00C3) or cardiac catheterization. With one of the following:

A. Cyanosis at rest, and:

1. Hematocrit of 55 percent or greater, or

2. Arterial O_2 saturation of less than 90 percent in room air, or resting arterial PO_2 of 60 Torr or less:

Or

B. Intermittent right-to-left shunting resulting in cyanosis on exertion (e.g., Eisenmenger's physiology) and with arterial PO_2 of 60 Torr or less at a workload equivalent to 5 METs or less;

Or

C. Chronic heart failure with evidence of ventricular dysfunction, as described in 4.02;

Or

D. Recurrent arrhythmias as described in 4.05;

Or

E. Secondary pulmonary vascular obstructive disease with a mean pulmonary arterial pressure elevated to at least 70 percent of the mean systemic arterial pressure.

4.07 ***Valvular heart disease or other stenotic defects, or valvular regurgitation,*** documented by appropriate imaging techniques or cardiac catheterization. Evaluate under the criteria in 4.02, 4.04, 4.05, or 11.04.

4.08 ***Cardiomyopathies,*** documented by appropriate imaging techniques or cardiac catheterization. Evaluate under the criteria in 4.02, 4.04, 4.05 or 11.04.

4.09 ***Cardiac transplantation***. Consider under a disability for 1 year following surgery; thereafter, reevaluate residual impairment under 4.02 to 4.08.

4.10 ***Aneurysm of aorta or major branches,*** due to any cause (e.g., atherosclerosis, cystic medial necrosis, Marfan syndrome, trauma), demonstrated by an appropriate imaging technique. With one of the following:

A. Acute or chronic dissection not controlled by prescribed medical or surgical treatment;

Or

B. Chronic heart failure as described under 4.02;

Or

C. Renal failure as described under 6.02;

Or

D. Neurological complications as described under 11.04.

4.11 ***Chronic venous insufficiency*** of a lower extremity. With incompetency or obstruction of the deep venous system and one of the following;

A. Extensive brawny edema;

Or

B. Superficial varicosities, stasis dermatitis, and recurrent or persistent ulceration which has not healed following at least 3 months of prescribed medical or surgical therapy.

4.12 ***Peripheral arterial disease***. With one of the following:

A. Intermittent claudication with failure to visualize (on arteriogram obtained independent of Social Security disability evaluation) the common femoral or deep femoral artery in one extremity;

Or

B. Intermittent claudication with marked impairment of peripheral arterial circulation as determined by Doppler studies showing:

1. Resting ankle/brachial systolic blood pressure ratio of less than 0.50; or

2. Decrease in systolic blood pressure at the ankle on exercise (see 4.00E4) of 50 percent or more of pre-exercise level at the ankle, and requiring 10 minutes or more to return to pre-exercise level.

5.00 Digestive System

A. *Disorders of the Digestive System* which result in a marked impairment usually do so because of interference with nutrition, multiple recurrent inflammatory lesions, or complications of disease, such as fistulae, abscesses, or recurrent obstruction. Such complications usually respond to treatment. These complications must be shown to persist on repeated examinations despite therapy for a reasonable presumption to be made that a marked impairment will last for a continuous period of at least 12 months.

B. *Malnutrition or Weight Loss* from gastrointestinal disorders. When the primary disorder of the digestive tract has been established (e.g., enterocolitis, chronic pancreatitis, postgastrointestinal resection, or esophageal stricture, stenosis, or obstruction), the resultant interference with nutrition will be considered under the criteria in 5.08. This will apply whether the weight loss is due to primary or secondary disorders of malabsorption, malassimilation or obstruction.

C. *Surgical Diversion of the Intestinal Tract,* including colostomy or ileostomy, are not listed since they do not represent impairments which preclude all work activity if the individual is able to maintain adequate nutrition and function of the stoma. Dumping syndrome which may follow gastric resection rarely represents a marked impairment which would continue for 12 months. Peptic ulcer disease with recurrent ulceration after definitive surgery ordinarily responds to treatment. To be considered a severe impairment which will last for at least 12 months, a recurrent ulcer after definitive surgery must be demonstrated, despite therapy, by repeated appropriate medically acceptable imaging of the upper gastrointestinal tract or by gastroscopic examinations. Medically acceptable imaging includes, but is not limited to, x-ray imaging, computerized axial tomography (CAT scan) or magnetic resonance imaging (MRI), with or without contrast material, myelography, and radionuclear bone scans. “Appropriate” means that the technique used is the proper one to support the evaluation and diagnosis of the impairment.

Definitive surgical procedures are those designed to control the ulcer disease process (i.e, vagotomy and pyloroplasty, subtotal gastrectomy, etc.). Simple closure of a perforated ulcer does not constitute definitive surgical therapy for peptic ulcer disease.

5.01 Category of Impairments, Digestive System

5.02 ***Recurrent Upper Gastrointestinal Hemorrhage from undetermined cause*** with anemia manifested by hematocrit of 30 percent or less on repeated examinations.

5.03 ***Stricture, stenosis, or obstruction of the esophagus (demonstrated by endoscopy or other appropriate medically acceptable imaging)*** with weight loss as described under listing 5.08.

5.04 ***Peptic ulcer disease (demonstrated by endoscopy or other appropriate medically acceptable imaging)***. With:

A. Recurrent ulceration after definitive surgery persistent despite therapy; or

B. Inoperable fistula formation; or

C. Recurrent obstruction demonstrated by endoscopy or other appropriate medically acceptable imaging; or

D. Weight loss as described under 5.08.

5.05 ***Chronic liver disease (e.g., portal, postnecrotic, or biliary cirrhosis; chronic active hepatitis; Wilson's disease)***. With:

A. Esophageal varices (demonstrated by endoscopy or other appropriate medically acceptable imaging) with a documented history of massive hemorrhage attributable to these varices.

Consider under disability for 3 years following the last massive hemorrhage; thereafter, evaluate the residual impairment; or

B. Performance of a shunt operation for esophageal varices. Consider under a disability for 3 years following surgery; thereafter, evaluate the residual impairment; or

C. Serum bilirubin of 2.5 mg. per deciliter (100 ml.) or greater persisting on repeated examinations for at least 5 months; or

D. Ascites, not attributable to other causes, recurrent or persisting for at least 5 months, demonstrated by abdominal paracentesis or associated with persistent hypoalbuminemia of 3.0 gm. per deciliter (100 ml.) or less; or

E. Hepatic encephalopathy. Evaluate under the criteria in Listing 12.02; or

F. Confirmation of chronic liver disease by liver biopsy (obtained independent of Social Security disability evaluation) and one of the following:

1. Ascites not attributable to other causes, recurrent or persisting for at least 3 months, demonstrated by abdominal paracentesis or associated with persistent hypoalbuminemia of 3.0 gm. per deciliter (100 ml.) or less; or

2. Serum bilirubin of 2.5 mg. per deciliter (100 ml.) or greater on repeated examinations for at least 3 months; or

3. Hepatic cell necrosis or inflammation, persisting for at least 3 months, documented by repeated abnormalities of prothrombin time and enzymes indicative of hepatic dysfunction.

5.06 ***Chronic Ulcerative or Granulomatous Colitis (demonstrated by endoscopy barium enema, biopsy, or operative findings)***. With:

A. Recurrent Bloody Stools documented on repeated examinations and anemia manifested by hematocrit of 30 percent or less on repeated examinations; or

B. Persistent or recurrent systemic manifestations. such as arthritis, iritis, fever, or liver dysfunction, not attributable to other causes; or

C. Intermittent obstruction due to intractable abscess, fistula formation, or stenosis; or

D. Recurrence of findings of A, B, or C, above after total colectomy: or

E. Weight loss as described under 5.08.

5.07 ***Regional Enteritis*** (Demonstrated by operative findings, barium studies, biopsy, or endoscopy). With:

A. Persistent or recurrent intestinal obstruction evidenced by abdominal pain, distention, nausea, and vomiting and accompanied by stenotic areas of small bowel with proximal intestinal dilation; or

B. Persistent or recurrent systemic manifestations such as arthritis, iritis, fever, or liver dysfunction, not attributable to other causes; or

C. Intermittent obstruction due to intractable abscess or fistula formation; or

D. Weight loss as described under 5.08.

5.08 ***Weight Loss due to any persisting gastrointestinal disorder****:* (The following weights are to be demonstrated to have persisted for at least 3 months despite prescribed therapy and expected to persist at this level for at least 12 months.) With:

A. Weight equal to or less than the values specified in Table I or II; or

B. Weight equal to or less than the values specified in Table III or IV and one of the following abnormal findings on repeated examinations:

1. Serum albumin of 3.0 gm. per deciliter (100 ml.) or less; or

2. Hematocrit of 30 percent or less; or

3. Serum calcium of 8.0 mg. per deciliter (100 ml.) (4.0 mEq./L) or less; or

4. Uncontrolled diabetes mellitus due to pancreatic dysfunction with repeated hyperglycemia, hypoglycemia, or ketosis; or

5. Fat in stool of 7 gm. or greater per 24-hour stool specimen; or

6. Nitrogen in stool of 3 gm. or greater per 24-hour specimen; or

7. Persistent or recurrent ascites or edema not attributable to other causes.

Tables of Weight Reflecting Malnutrition Scaled According to Height and Sex--to be used only in connection with 5.08.

Table I – Men

Height without Shoes (inches)	Weight (pounds)
61	 90
62	 92
63	 94
64	 97
65	 99
66	 102
67	 106
68	 109
69	 112
70	 115
71	 118
72	 122
73	 125
74	 128
75	 131
76	 134

Table II – Women

Height without shoe (inches)	Weight (pounds)
58	77
59	79
60	82
61	84
62	86
63	89
64	91
65	94
66	98
67	101
68	104
69	107
70	110
71	114
72	117
73	120

Table III - Men

Height without Shoes (inches)	Weight (pounds)
61	 95
62	 98
63	 100
64	 103
65	 106
66	 109
67	 112
68	 116
69	 119
70	 122
71	 126
72	 129
73	 133
74	 136
75	 139
76	 143

Table IV – Women

Height without shoe (inches)	Weight (pounds)
58	82
59	84
60	87
61	89
62	92
63	94
64	97
65	100
66	104
67	107
68	111
69	114
70	117
71	121
72	124
73	128

5.09 ***Liver transplant***. Consider under a disability for 12 months following the date of the surgery; thereafter, evaluate the residual impairment(s).

6.00 Genito-Urinary System

A. *Determination of the presence of chronic renal disease* will be based upon (1) a history, physical examination, and laboratory evidence of renal disease, and (2) indications of its progressive nature or laboratory evidence of deterioration of renal function. Medically acceptable imaging includes, but is not limited to, x-ray imaging, computerized axial tomography (CAT scan) or magnetic resonance imaging (MRI), with or without contrast material, myelography, and radiocnuclear bone scans. "Appropriate" means that the technique used is the proper one to support the evaluation and diagnosis of the impairment.

B. *Nephrotic Syndrome.* The medical evidence establishing the clinical diagnosis must include the description of extent of tissue edema, including pretibial, periorbital, or presacral edema. The presence of ascites, pleural effusion, pericardial effusion, and hydroarthrosis should be described if present. Results of pertinent laboratory tests must be provided. If a renal biopsy has been performed, the evidence should include a copy of the report of microscopic examination of the specimen. Complications such as severe orthostatic hypotension, recurrent infections or venous thromboses should be evaluated on the basis of resultant impairment.

C. *Hemodialysis, peritoneal dialysis, and kidney transplantation.* When an individual is undergoing periodic dialysis because of chronic renal disease, severity of impairment is reflected by the renal function prior to the institution of dialysis.

The amount of function restored and the time required to effect improvement in an individual treated by renal transplant depend upon various factors, including adequacy of post transplant renal function, incidence and severity of renal infection, occurrence of rejection crisis, the presence of systemic complications (anemia, neuropathy, etc.), and side effects of corticosteroids or immuno-suppressive agents. A convalescent period of at least 12 months is required before it can be reasonably determined whether the individual has reached a point of stable medical improvement.

D. *Evaluate associated disorders and complications* according to the appropriate body system Listing.

6.01 Category of Impairments, Genito-Urinary System

6.02 ***Impairment of Renal Function,*** due to any chronic renal disease expected to last 12 months (e.g., hypertensive vascular disease, chronic nephritis, nephrolithiasis, polycystic disease, bilateral hydronephrosis, etc.) With:

A. *Chronic hemodialysis or peritoneal dialysis* necessitated by irreversible renal failure; or

B. *Kidney transplant.* Consider under a disability for 12 months following surgery; thereafter, evaluate the residual impairment (see 6.00C); or

C. *Persistent elevation of serum creatinine* to 4 mg. per deciliter (100 ml.) or greater or reduction of creatinine clearance to 20 ml. per minute (29 liters/24 hours) or less, over at least 3 months, with one of the following:

1. *Renal osteodystrophy* manifested by severe bone pain and abnormalities shown by appropriate medically acceptable imaging (e.g., osteitis fibrosa, marked osteoporosis, pathologic fractures); or

2. A *clinical episode of pericarditis;* or

3. *Persistent motor or sensory neuropathy;* or

4. *Intractable pruritus;* or

5. *Persistent fluid overload syndrome* resulting in diastolic hypertension (110 mm. or above) or signs of vascular congestion; or

6. *Persistent anorexia* with recent weight loss and current weight meeting the values in 5.08, Table III or IV; or

7. *Persistent hematocrits* of 30 percent or less.

6.06 ***Nephrotic syndrome, with significant anasarca, persistent for at least 3 months despite prescribed therapy***. With:

A. *Serum albumin* of 3.0 gm. per deciliter (100 ml.) or less and proteinuria of 3.5 gm. per 24 hours or greater; or

B. *Proteinuria of* 10.0 gm. per 24 hours or greater.

7.00 Hematological Disorders

A. *Impairment caused by anemia* should be evaluated according to the ability of the individual to adjust to the reduced oxygen-carrying capacity of the blood. *A* gradual reduction in red cell mass, even to very low values, is often well tolerated in individuals with a healthy cardiovascular system.

B. *Chronicity is indicated* by persistence of the condition for at least 3 months. The laboratory findings cited must reflect the values reported on more than one examination over that 3-month period. Medically acceptable imaging includes, but is not limited to, x-ray imaging, computerized axial tomography (CAT scan) or magnetic resonance imaging (MRI), with or without contrast material, myelography, and radionuclear bone scans. "Appropriate" means that the technique used is the proper one to support the evaluation and diagnosis of the impairment.

C. *Sickle cell disease* refers to a chronic hemolytic anemia associated with sickle cell hemoglobin, either homozygous or in combination with thalassemia or with another abnormal hemoglobin (such as C or F).

Appropriate hematologic evidence for sickle cell disease, such as hemoglobin electrophoresis, must be included. Vaso-occlusive or aplastic episodes should be documented by description of severity, frequency, and duration.

Major visceral episodes include meningitis, osteomyelitis, pulmonary infections or infarctions, cerebrovascular accidents, congestive heart failure, genito-urinary involvement, etc.

D. *Coagulation defects.* Chronic inherited coagulation disorders must be documented by appropriate laboratory evidence. Prophylactic therapy such as with antihemophilic globulin (AHG) concentrate does not in itself imply severity.

7.01 Category of Impairments, Hematological Disorders

7.02 ***Chronic anemia (hematocrit persisting*** *at 30 percent or less due to any cause)* With:

A. Requirement of one or more blood transfusions on an average of at least once every 2 months; or

B. Evaluation of the resulting impairment under criteria for the affected body system.

7.05 ***Sickle cell disease, or one of its variants***. With:

A. Documented painful (thrombotic) crises occurring at least three times during the *5* months prior to adjudication; or

B. Requiring extended hospitalization (beyond emergency care) at least three times during the 12 months prior to adjudication; or

C. Chronic, severe anemia with persistence of hematocrit of 26 percent or less; or

D. Evaluate the resulting impairment under the criteria for the affected body system.

7.06 ***Chronic thrombocytopenia (due to any cause),*** with platelet counts repeatedly below 40,000/ cubic millimeter. With:

A. At least one spontaneous hemorrhage, requiring transfusion, within 5 months prior to adjudication; or

B. Intracranial bleeding within 12 months prior to adjudication.

7.07 ***Hereditary telangiectasia*** with hemorrhage requiring transfusion at least three times during the 5 months prior to adjudication.

7.08 ***Coagulation defects (hemophilia or a similar disorder)*** with spontaneous hemorrhage requiring transfusion at least three times during the 5 months prior to adjudication.

7.09 ***Polycythemia vera (with erythrocytosis, splenomegaly, and leukocytosis or thrombocytosis)***. Evaluate the resulting impairment under the criteria for the affected body system.

7.10 ***Myelofibrosis (myeloproliferative syndrome)***. With:

A. Chronic anemia. Evaluate according to the criteria of 7.02; or

B. Documented recurrent systemic bacterial infections occurring at least 3 times during the 5 months prior to adjudication; or

C. Intractable bone pain with radiologic evidence of osteosclerosis.

7.15 ***Chronic granulocytopenia (due to any cause)***. With both A and B:

A. Absolute neutrophil counts repeatedly below 1,000 cells/cubic millimeter; and

B. Documented recurrent systemic bacterial infections occurring at least 3 times during the 5 months prior to adjudication.

7.17 ***Aplastic anemias with bone marrow or stem cell transplantation.*** Consider under a disability for 12 months following transplantation; thereafter, evaluate according to the primary characteristics of the residual impairment.

8.00 Skin Disorders

A. *What skin disorders do we evaluate with these listings?* We use these listings to evaluate skin disorders that may result from hereditary, congenital, or acquired pathological processes. The kinds of impairments covered by these listings are: Ichthyosis, bullous diseases, chronic infections of the skin or mucous membranes, dermatitis, hidradenitis suppurativa, genetic photosensitivity disorders, and burns.

B. *What documentation do we need?* When we evaluate the existence and severity of your skin disorder, we generally need information about the onset, duration, frequency of flare-ups, and prognosis of your skin disorder; the location, size, and appearance of lesions; and, when applicable, history of exposure to toxins, allergens, or irritants, familial incidence, seasonal variation, stress factors, and your ability to function outside of a highly protective environment. To confirm the diagnosis, we may need laboratory findings (for example, results of a biopsy obtained independently of Social Security disability evaluation or blood tests) or evidence from other medically acceptable methods consistent with the prevailing state of medical knowledge and clinical practice.

C. *How do we assess the severity of your skin disorder(s)?* We generally base our assessment of severity on the extent of your skin lesions, the frequency of flare-ups of your skin lesions, how your symptoms (including pain) limit you, the extent of your treatment, and how your treatment affects you.

1. *Extensive skin lesions.* Extensive skin lesions are those that involve multiple body sites or critical body areas, and result in a very serious limitation. Examples of extensive skin lesions that result in a very serious limitation include but are not limited to:

a. Skin lesions that interfere with the motion of your joints and that very seriously limit your use of more than one extremity; that is, two upper extremities, two lower extremities, or one upper and one lower extremity.

b. Skin lesions on the palms of both hands that very seriously limit your ability to do fine and gross motor movements.

c. Skin lesions on the soles of both feet, the perineum, or both inguinal areas that very seriously limit your ability to ambulate.

2. *Frequency of flare-ups.* If you have skin lesions, but they do not meet the requirements of any of the listings in this body system, you may still have an impairment that prevents you from doing any gainful activity when we consider your condition over time, especially if your flare-ups result in extensive skin lesions, as defined in C1 of this section. Therefore, if you have frequent flare-ups, we may find that your impairment(s) is medically equal to one of these listings even though you have some periods during which your condition is in remission. We will consider how frequent and serious your flare-ups are, how quickly they resolve, and how you function between

flare-ups to determine whether you have been unable to do any gainful activity for a continuous period of at least 12 months or can be expected to be unable to do any gainful activity for a continuous period of at least 12 months. We will also consider the frequency of your flare-ups when we determine whether you have a severe impairment and when we need to assess your residual functional capacity.

3. *Symptoms (including pain).* Symptoms (including pain) may be important factors contributing to the severity of your skin disorder(s). We assess the impact of symptoms as explained in §§ 404.1528, 404.1529, 416.928, and 416.929 of this chapter.

4. *Treatment.* We assess the effects of medication, therapy, surgery, and any other form of treatment you receive when we determine the severity and duration of your impairment(s). Skin disorders frequently respond to treatment; however, response to treatment can vary widely, with some impairments becoming resistant to treatment. Some treatments can have side effects that can in themselves result in limitations.

a. We assess the effects of continuing treatment as prescribed by determining if there is improvement in the symptoms, signs, and laboratory findings of your disorder, and if you experience side effects that result in functional limitations. To assess the effects of your treatment, we may need information about:

i. The treatment you have been prescribed (for example, the type, dosage, method, and frequency of administration of medication or therapy);

ii. Your response to the treatment;

iii. Any adverse effects of the treatment; and

iv. The expected duration of the treatment.

b. Because treatment itself or the effects of treatment may be temporary, in most cases sufficient time must elapse to allow us to evaluate the impact and expected duration of treatment and its side effects. Except under 8.07 and 8.08, you must follow continuing treatment as prescribed for at least 3 months before your impairment can be determined to meet the requirements of a skin disorder listing. (See 8.00H if you are not undergoing treatment or did not have treatment for 3 months.) We consider your specific response to treatment when we evaluate the overall severity of your impairment.

D. *How do we assess impairments that may affect the skin and other body systems?* When your impairment affects your skin and has effects in other body systems, we first evaluate the predominant feature of your impairment under the appropriate body system. Examples include, but are not limited to the following.

1. *Tuberous sclerosis* primarily affects the brain. The predominant features are seizures, which we evaluate under the neurological listings in 11.00, and developmental delays or other mental disorders, which we evaluate under the mental disorders listings in 12.00.

2. *Malignant tumors of the skin* (for example, malignant melanomas) are cancers, or neoplastic diseases, which we evaluate under the listings in 13.00.

3. *Connective tissue disorders and other immune system disorders* (for example, systemic lupus erythematosus, scleroderma, human immunodeficiency virus (HIV) infection, and Sjögren's syndrome) often involve more than one body system. We first evaluate these disorders under the immune system listings in 14.00. We evaluate lupus erythematosus under 14.02, scleroderma under 14.04, symptomatic HIV infection under 14.08, and Sjögren's syndrome under 14.03, 14.09, or any other appropriate listing in section 14.00.

4. *Disfigurement or deformity* resulting from skin lesions may result in loss of sight, hearing, speech, and the ability to chew (mastication). We evaluate these impairments and their effects under the special senses and speech listings in 2.00 and the digestive system listings in 5.00. Facial disfigurement or other physical deformities may also have effects we evaluate under the mental disorders listings in 12.00, such as when they affect mood or social functioning.

E. *How do we evaluate genetic photosensitivity disorders?*

1. *Xeroderma pigmentosum (XP).* When you have XP, your impairment meets the requirements of 8.07A if you have clinical and laboratory findings showing that you have the disorder. (See 8.00E3.) People who have XP have a lifelong hypersensitivity to all forms of ultraviolet light and generally lead extremely restricted lives in highly protective environments in order to prevent skin cancers from developing. Some people with XP also experience problems with their eyes, neurological problems, mental disorders, and problems in other body systems.

2. *Other genetic photosensitivity disorders.* Other genetic photosensitivity disorders may vary in their effects on different people, and may not result in an inability to engage in any gainful activity for a continuous period of at least 12 months. Therefore, if you have a genetic photosensitivity disorder other than XP (established by clinical and laboratory findings as described in 8.00E3), you must show that you have either extensive skin lesions or an inability to function outside of a highly protective environment to meet the requirements of 8.07B. You must also show that your impairment meets the duration requirement. By *inability to function outside of a highly protective environment* we mean that you must avoid exposure to ultraviolet light (including sunlight passing through windows and light from unshielded fluorescent bulbs), wear protective clothing and eyeglasses, and use opaque broad spectrum sunscreens in order to avoid skin cancer or other serious effects. Some genetic photosensitivity disorders can have very serious effects in other body systems, especially special senses and speech (2.00), neurological (11.00), mental (12.00), and neoplastic (13.00). We will evaluate the predominant feature of your impairment under the appropriate body system, as explained in 8.00D.

3. *Clinical and laboratory findings.* We need evidence confirming the diagnosis of your XP or other genetic photosensitivity disorder. The evidence must include a clinical description of abnormal physical findings associated with the condition. There must also be definitive genetic laboratory studies documenting appropriate chromosomal damage, abnormal DNA repair, or other DNA or genetic abnormality specific to your type of photosensitivity disorder. However, we do not need a copy of the actual laboratory report if we have medical evidence that is persuasive that a positive diagnosis has been confirmed by laboratory testing.

F. *How do we evaluate burns?* Electrical, chemical, or thermal burns frequently affect other body systems; for example, musculoskeletal, special senses and speech, respiratory, cardiovascular, renal, neurological, or mental. Consequently, we evaluate burns the way we evaluate other disorders that can affect the skin and other body systems, using the listing for the predominant feature of your impairment. For example, if your soft tissue injuries are under continuing surgical management (as defined in 1.00M), we will evaluate your impairment under 1.08. However, if

your burns do not meet the requirements of 1.08 and you have extensive skin lesions that result in a very serious limitation (as defined in 8.00C1) that has lasted or can be expected to last for a continuous period of at least 12 months, we will evaluate them under 8.08.

G. *How do we determine if your skin disorder(s) will continue at a disabling level of severity in order to meet the duration requirement?* For all of these skin disorder listings except 8.07 and 8.08, we will find that your impairment meets the duration requirement if your skin disorder results in extensive skin lesions that persist for at least 3 months despite continuing treatment as prescribed. By *persist,* we mean that the longitudinal clinical record shows that, with few exceptions, your lesions have been at the level of severity specified in the listing. For 8.07A, we will presume that you meet the duration requirement. For 8.07B and 8.08, we will consider all of the relevant medical and other information in your case record to determine whether your skin disorder meets the duration requirement.

H. *How do we assess your skin disorder(s) if your impairment does not meet the requirements of one of these listings?*

1. These listings are only examples of common skin disorders that we consider severe enough to prevent you from engaging in any gainful activity. For most of these listings, if you do not have continuing treatment as prescribed, if your treatment has not lasted for at least 3 months, or if you do not have extensive skin lesions that have persisted for at least 3 months, your impairment cannot meet the requirements of these skin disorder listings. (This provision does not apply to 8.07 and 8.08.) However, we may still find that you are disabled because your impairment(s) meets the requirements of a listing in another body system or medically equals the severity of a listing. (See §§ 404.1526 and 416.926 of this chapter.) We may also find you disabled at the last step of the sequential evaluation process.

2. If you have not received ongoing treatment or do not have an ongoing relationship with the medical community despite the existence of a severe impairment(s), or if your skin lesions have not persisted for at least 3 months but you are undergoing continuing treatment as prescribed, you may still have an impairment(s) that meets a listing in another body system or that medically equals a listing. If you do not have an impairment(s) that meets or medically equals a listing, we will assess your residual functional capacity and proceed to the fourth and, if necessary, the fifth step of the sequential evaluation process in §§ 404.1520 and 416.920 of this chapter. When we decide whether you continue to be disabled, we use the rules in §§ 404.1594 and 416.994 of this chapter.

8.01 Category of Impairments, Skin Disorders

8.02 ***Ichthyosis,*** with extensive skin lesions that persist for at least 3 months despite continuing treatment as prescribed.

8.03 ***Bullous disease*** (for example, pemphigus, erythema multiforme bullosum, epidermolysis bullosa, bullous pemphigoid, dermatitis herpetiformis), with extensive skin lesions that persist for at least 3 months despite continuing treatment as prescribed.

8.04 ***Chronic infections of the skin or mucous membranes,*** with extensive fungating or extensive ulcerating skin lesions that persist for at least 3 months despite continuing treatment as prescribed.

8.05 ***Dermatitis*** (for example, psoriasis, dyshidrosis, atopic dermatitis, exfoliative dermatitis, allergic contact dermatitis), with extensive skin lesions that persist for at least 3 months despite continuing treatment as prescribed.

8.06 ***Hidradenitis suppurativa,*** with extensive skin lesions involving both axillae, both inguinal areas or the perineum that persist for at least 3 months despite continuing treatment as prescribed.

8.07 ***Genetic photosensitivity disorders,*** established by clinical and laboratory findings as described in 8.00E.

A. Xeroderma pigmentosum. Consider the individual disabled from birth.

B. Other genetic photosensitivity disorders, with:

1. Extensive skin lesions that have lasted or can be expected to last for a continuous period of at least 12 months, OR

2. Inability to function outside of a highly protective environment for a continuous period of at least 12 months (see 8.00E2).

8.08 ***Burns,*** with extensive skin lesions that have lasted or can be expected to last for a continuous period of at least 12 months (see 8.00F).

9.00 Endocrine System

Cause of impairment. Impairment is caused by overproduction or underproduction of hormones, resulting in structural or functional changes in the body. Where involvement of other organ systems has occurred as a result of a primary endocrine disorder, these impairments should be evaluated according to the criteria under the appropriate sections. Medically acceptable imaging includes, but is not limited to, x-ray imaging, computerized axial tomography (CAT scan) or magnetic resonance imaging (MRI), with or without contrast material, myelography, and radionuclear bone scans. "Appropriate" means that the technique used is the proper one to support the evaluation and diagnosis of the impairment.

9.01 Category of Impairments, Endocrine System

9.02 ***Thyroid Disorders***. Evaluate the resulting impairment under the criteria for the affected body system.

9.03 ***Hyperparathyroidism***. With:

A. *Generalized decalcification of bone* on appropriate medically acceptable imaging study and elevation of plasma calcium to 11 mg. per deciliter (100 ml) or greater; or

B. *A resulting impairment.* Evaluate according to the criteria in the affected body system.

9.04 ***Hypoparathyroidism***. With:

A. *Severe recurrent tetany;* or

B. *Recurrent generalized convulsions;* or

C. *Lenticular cataracts.* Evaluate under the criteria in 2.00ff.

9.05 ***Neurohypophyseal insufficiency (diabetes insipidus)***. With urine specific gravity of 1.005 or below, persistent for at least 3 months and recurrent dehydration.

9.06 ***Hyperfunction of the adrenal cortex***. Evaluate the resulting impairment under the criteria for the affected body system.

9.08 ***Diabetes mellitus***. With:

A. *Neuropathy* demonstrated by significant and persistent disorganization of motor function in two extremities resulting in sustained disturbance of gross and dexterous movements, or gait and station (see 11.00C); or

B. *Acidosis* occurring at least on the average of once every 2 months documented by appropriate blood chemical tests (pH or pC02 or bicarbonate levels); or

C. *Retinitis proliferans;* evaluate the visual impairment under the criteria in 2.02, 2.03, or 2.04.

10.00 Multiple Body Systems

A. Down syndrome (except for mosaic Down syndrome (see 10.00C)) established by clinical findings, including the characteristic physical features, and laboratory evidence is considered to meet the requirement of listing 10.06, commencing at birth.

B. Documentation must include confirmation of a positive diagnosis by a clinical description of the usual abnormal physical findings associated with the condition and definitive laboratory tests, including chromosomal analysis. Medical evidence that is persuasive that a positive diagnosis has been confirmed by appropriate laboratory testing, at some time prior to evaluation, is acceptable in lieu of a copy of the actual laboratory report.

C. Other chromosomal abnormalities; e.g., mosaic Down syndrome, fragile X syndrome, phenylketonuria, and fetal alcohol syndrome, produce a pattern of multiple impairments but manifest in a wide range of impairment severity. Therefore, the effects of these impairments should be evaluated under the affected body system.

10.01 Category of Impairments, Multiple Body Systems

10.06 ***Down syndrome (excluding mosaic Down syndrome)*** established by clinical and laboratory findings, as described in 10.00B. Consider the individual disabled from birth.

11.00 Neurological

A. *Epilepsy.* In epilepsy, regardless of etiology, degree of impairment will be determined according to type, frequency, duration, and sequelae of seizures. At least one detailed description of a typical seizure is required. Such description includes the presence or absence of aura, tongue bites, sphincter control, injuries associated with the attack, and postictal phenomena. The reporting physician should indicate the extent to which description of seizures reflects his own

observations and the source of ancillary information. Testimony of persons other than the claimant is essential for description of type and frequency of seizures if professional observation is not available.

Under 11.02 and 11.03, the criteria can be applied only if the impairment persists despite the fact that the individual is following prescribed antiepileptic treatment. Adherence to prescribed antiepileptic therapy can ordinarily be determined from objective clinical findings in the report of the physician currently providing treatment for epilepsy. Determination of blood levels of phenytoin sodium or other antiepileptic drugs may serve to indicate whether the prescribed medication is being taken. When seizures are occurring at the frequency stated in 11.02 or 11.03, evaluation of the severity of the impairment must include consideration of the serum drug levels. Should serum drug levels appear therapeutically inadequate, consideration should be given as to whether this is caused by individual idiosyncrasy in absorption or metabolism of the drug. Blood drug levels should be evaluated in conjunction with all other evidence to determine the extent of compliance. When the reported blood drug levels are low, therefore, the information obtained from the treating source should include the physician's statement as to why the levels are low and the results of any relevant diagnostic studies concerning the blood levels. Where adequate seizure control is obtained only with unusually large doses, the possibility of impairment resulting from the side effects of this medication must also be assessed. Where documentation shows that use of alcohol or drugs affects adherence to prescribed therapy or may play a part in the precipitation of seizures, this must also be considered in the overall assessment of impairment level.

B. *Brain tumors*. We evaluate malignant brain tumors under the criteria in 13.13. For benign brain tumors, we determine the severity and duration of the impairment on the basis of symptoms, signs, and laboratory findings (11.05).

C. *Persistent disorganization of motor function* in the form of paresis or paralysis, tremor or other involuntary movements, ataxia and sensory disturbances (any or all of which may be due to cerebral, cerebellar, brain stem, spinal cord, or peripheral nerve dysfunction) which occur singly or in various combinations, frequently provides the sole or partial basis for decision in cases of neurological impairment. The assessment of impairment depends on the degree of interference with locomotion and/or interference with the use of fingers, hands and arms.

D. *In conditions which are episodic in character,* such as multiple sclerosis or myasthenia gravis, consideration should be given to frequency and duration of exacerbations, length of remissions, and permanent residuals.

E. *Multiple sclerosis.* The major criteria for evaluating impairment caused by multiple sclerosis are discussed in Listing 11.09. Paragraph A provides criteria for evaluating disorganization of motor function and gives reference to 11.04B (11.04B then refers to 11.00C). Paragraph B provides references to other listings for evaluating visual or mental impairments caused by multiple sclerosis. Paragraph C provides criteria for evaluating the impairment of individuals who do not have muscle weakness or other significant disorganization of motor function at rest, but who do develop muscle weakness on activity as a result of fatigue.

Use of the criteria in 11.09C is dependent upon (1) documenting a diagnosis of multiple sclerosis, (2) obtaining a description of fatigue considered to be characteristic of multiple sclerosis, and (3) obtaining evidence that the system has actually become fatigued. The evaluation of the magnitude of the impairment must consider the degree of exercise and the severity of the resulting muscle weakness.

The criteria in 11.09C deal with motor abnormalities which occur on activity. If the disorganization of motor function is present at rest, paragraph A must be used, taking into account any further increase in muscle weakness resulting from activity.

Sensory abnormalities may occur, particularly involving central visual acuity. The decrease in visual acuity may occur after brief attempts at activity involving near vision, such as reading. This decrease in visual acuity may not persist when the specific activity is terminated, as with rest, but is predictably reproduced with resumption of the activity. The impairment of central visual acuity in these cases should be evaluated under the criteria in Listing 2.02, taking into account the fact that the decrease in visual acuity will wax and wane.

Clarification of the evidence regarding central nervous system dysfunction responsible for the symptoms may require supporting technical evidence of functional impairment such as evoked response tests during exercise.

F. *Traumatic brain injury (TBI)*. The guidelines for evaluating impairments caused by cerebral trauma are contained in 11.18. Listing 11.18 states that cerebral trauma is to be evaluated under 11.02, 11.03, 11.04, and 12.02, as applicable.

TBI may result in neurological and mental impairments with a wide variety of posttraumatic symptoms and signs. The rate and extent of recovery can be highly variable and the long-term outcome may be difficult to predict in the first few months post-injury. Generally, the neurological impairment (s) will stabilize more rapidly than any mental impairment (s). Sometimes a mental impairment may appear to improve immediately following TBI and then worsen, or, conversely, it may appear much worse initially but improve after a few months. Therefore, the mental findings immediately following TBI may not reflect the actual severity of your mental impairment (s). The actual severity of a mental impairment may not become apparent until 6 months post-injury.

In some cases, evidence of a profound neurological impairment is sufficient to permit a finding of disability within 3 months post-injury. If a finding of disability within 3 months post-injury is not possible based on any neurological impairment (s), we will defer adjudication of the claim until we obtain evidence of your neurological or mental impairments at least 3 months post-injury. If a finding of disability still is not possible at that time, we will again defer adjudication of the claim until we obtain evidence at least 6 months post-injury. At that time, we will fully evaluate any neurological and mental impairments and adjudicate the claim.

G. *Amyotrophic Lateral Sclerosis (ALS)*.

1. Amyotrophic lateral sclerosis (ALS), sometimes called Lou Gehrig's disease, is a progressive, invariably fatal neurological disease that attacks the nerve cells (motor neurons) responsible for controlling voluntary muscles. Eventually, all muscles under voluntary control are affected, and individuals with ALS ultimately lose their ability to move their arms and legs, and their capacity to swallow, speak, and breath. Most people with ALS die from respiratory failure. There is currently no cure for ALS, and most treatments are designed only to relieve symptoms and improve the quality of life.

2. Diagnosis of ALS is based on history, neurological findings consistent with the diagnosis of ALS, and electrophysiological and neuroimaging testing to rule out other impairments that may cause similar signs and symptoms. The diagnosis may also be supported by electrophysiological

studies (electromyography or nerve conduction studies), but these tests may be negative or only suggestive of the diagnosis. There is no single test that establishes the existence of ALS.

3. For purposes of 11.10, documentation of the diagnosis must be by generally accepted methods consistent with the prevailing state of medical knowledge and clinical practice. The evidence should include documentation of a clinically appropriate medical history, neurological findings consistent with the diagnosis of ALS, and the results of any electrophysiological and neuroimaging testing.

11.01 Category of Impairments, Neurological

11.02 ***Epilepsy – convulsive epilepsy (grand mal or psychomotor), documented by detailed description of a typical seizure pattern, including all associated phenomena; occurring more frequently than once a month, in spite of at least 3 months of prescribed treatment.*** With:

A. Daytime episodes (loss of consciousness and convulsive seizures) or

B. Nocturnal episodes manifesting residuals which interfere significantly with activity during the day.

11.03 ***Epilepsy -- nonconvulsive epilepsy (petit mal, psychomotor, or focal) documented by detailed description of a typical seizure pattern, including all associated phenomena, occurring more frequently than once weekly, in spite of at least 3 months of prescribed treatment.*** With alteration of awareness or loss of consciousness and transient postictal manifestations of unconventional behavior or significant interference with activity during the day.

11.04 ***Central nervous system vascular accident.*** With one of the following more than 3 months post-vascular accident:

A. Sensory or motor aphasia resulting in ineffective speech or communication; or

B. Significant and persistent disorganization of motor function in two extremities, resulting in sustained disturbance of gross and dexterous movements, or gait and station (see 11.00C).

11.05 ***Benign Brain tumors.*** Evaluate under 11.02, 11.03, 11.04 or the criteria of the affected body system.

11.06 ***Parkinsonian syndrome*** with the following signs: Significant rigidity, bradykinesia, or tremor in two extremities, which, singly or in combination, result in sustained disturbance of gross and dexterous movements, or gait and station.

11.07 ***Cerebral palsy.*** With:

A. IQ of 70 or less; or

B. Abnormal behavior patterns, such as destructiveness or emotional instability; or

C. Significant interference in communication due to speech, hearing, or visual defect; or

D. Disorganization of motor function as described in 11.04B.

11.08 ***Spinal cord or nerve root lesions, due to any cause*** with disorganization of motor function as described in 11.04B.

11.09 ***Multiple sclerosis***. With:

A. Disorganization of motor function as described in 11.04B; or

B. Visual or mental impairment as described under the criteria in 2.02, 2.03, 2.04, or 12.02; or

C. Significant, reproducible fatigue of motor function with substantial muscle weakness on repetitive activity, demonstrated on physical examination, resulting from neurological dysfunction in areas of the central nervous system known to be pathologically involved by the multiple sclerosis process.

11.10 ***Amyotrophic lateral sclerosis*** established by clinical and laboratory findings, as described in 11.00G.

11.11 ***Anterior poliomyelitis***. With:

A. Persistent difficulty with swallowing or breathing; or

B. Unintelligible speech; or

C. Disorganization of motor function as described in 11.04B.

11.12 ***Myasthenia gravis.*** **With:**

A. Significant difficulty with speaking, swallowing, or breathing while on prescribed therapy; or

B. Significant motor weakness of muscles of extremities on repetitive activity against resistance while on prescribed therapy.

11.13 ***Muscular dystrophy*** with disorganization of motor function as described in 11.04B.

11.14 ***Peripheral neuropathies***. With disorganization of motor function as described in 11.04B, in spite of prescribed treatment.

11.15 (Reserved)

11.16 ***Subacute combined cord degeneration (pernicious anemia) with disorganization of motor function as described in 11.04B or 11.15B, not significantly improved by prescribed treatment.***

11.17 ***Degenerative disease not listed elsewhere, such as Huntington's chorea, Friedreich's ataxia, and spino-cerebellar degeneration***. With:

A. Disorganization of motor function as described in 11.04B; or

B. Chronic brain syndrome. Evaluate under 12.02.

11.18 ***Cerebral trauma***.

Evaluate under the provisions of 11.02, 11.03, 11.04, and 12.02, as applicable.

11.19 ***Syringomyelia***. With:

A. Significant bulbar signs; or

B. Disorganization of motor function as described in 11.04B.

12.00 Mental Disorders

A. *Introduction*: The evaluation of disability on the basis of mental disorders requires documentation of a medically determinable impairment(s), consideration of the degree of limitation such impairment(s) may impose on the individual's ability to work, and consideration of whether these limitations have lasted or are expected to last for a continuous period of at least 12 months. The listings for mental disorders are arranged in nine diagnostic categories: Organic mental disorders (12.02); schizophrenic, paranoid and other psychotic disorders (12.03); affective disorders (12.04); mental retardation (12.05); anxiety-related disorders (12.06); somatoform disorders (12.07); personality disorders (12.08); substance addiction disorders (12.09); and autistic disorder and other pervasive developmental disorders (12.10). Each listing, except 12.05 and 12.09, consists of a statement describing the disorder(s) addressed by the listing, paragraph A criteria (a set of medical findings), and paragraph B criteria (a set of impairment-related functional limitations). There are additional functional criteria (paragraph C criteria) in 12.02, 12.03, 12.04, and 12.06, discussed herein. We will assess the paragraph B criteria before we apply the paragraph C criteria. We will assess the paragraph C criteria only if we find that the paragraph B criteria are not satisfied. We will find that you have a listed impairment if the diagnostic description in the introductory paragraph and the criteria of both paragraphs A and B (or A and C, when appropriate) of the listed impairment are satisfied.

The criteria in paragraph A substantiate medically the presence of a particular mental disorder. Specific symptoms, signs, and laboratory findings in the paragraph A criteria of any of the listings in this section cannot be considered in isolation from the description of the mental disorder contained at the beginning of each listing category. Impairments should be analyzed or reviewed under the mental category(ies) indicated by the medical findings. However, we may also consider mental impairments under physical body system listings, using the concept of medical equivalence, when the mental disorder results in physical dysfunction. (See, for instance, 12.00D12 regarding the evaluation of anorexia nervosa and other eating disorders.)

The criteria in paragraphs B and C describe impairment-related functional limitations that are incompatible with the ability to do any gainful activity. The functional limitations in paragraphs B and C must be the result of the mental disorder described in the diagnostic description that is manifested by the medical findings in paragraph A.

The structure of the listing for mental retardation (12.05) is different from that of the other mental disorders listings. Listing 12.05 contains an introductory paragraph with the diagnostic description for mental retardation. It also contains four sets of criteria (paragraphs A through D). If your impairment satisfies the diagnostic description in the introductory paragraph and any one of the four sets of criteria, we will find that your impairment meets the listing. Paragraphs A and B contain criteria that describe disorders we consider severe enough to prevent your doing any gainful activity without any additional assessment of functional limitations. For paragraph C, we

will assess the degree of functional limitation the additional impairment(s) imposes to determine if it significantly limits your physical or mental ability to do basic work activities, i.e., is a "severe" impairment(s), as defined in §§ 404.1520(c) and 416.920(c). If the additional impairment(s) does not cause limitations that are "severe" as defined in §§ 404.1520(c) and 416.920(c), we will not find that the additional impairment(s) imposes "an additional and significant work-related limitation of function," even if you are unable to do your past work because of the unique features of that work. Paragraph D contains the same functional criteria that are required under paragraph B of the other mental disorders listings.

The structure of the listing for substance addiction disorders, 12.09, is also different from that for the other mental disorder listings. Listing 12.09 is structured as a reference listing; that is, it will only serve to indicate which of the other listed mental or physical impairments must be used to evaluate the behavioral or physical changes resulting from regular use of addictive substances. The listings are so constructed that an individual with an impairment(s) that meets or is equivalent in severity to the criteria of a listing could not reasonably be expected to do any gainful activity. These listings are only examples of common mental disorders that are considered severe enough to prevent an individual from doing any gainful activity. When you have a medically determinable severe mental impairment that does not satisfy the diagnostic description or the requirements of the paragraph A criteria of the relevant listing, the assessment of the paragraph B and C criteria is critical to a determination of equivalence.

If your impairment(s) does not meet or is not equivalent in severity to the criteria of any listing, you may or may not have the residual functional capacity (RFC) to do substantial gainful activity (SGA). The determination of mental RFC is crucial to the evaluation of your capacity to do SGA when your impairment(s) does not meet or equal the criteria of the listings, but is nevertheless severe.

RFC is a multidimensional description of the work-related abilities you retain in spite of your medical impairments. An assessment of your RFC complements the functional evaluation necessary for paragraphs B and C of the listings by requiring consideration of an expanded list of work-related capacities that may be affected by mental disorders when your impairment(s) is severe but neither meets nor is equivalent in severity to a listed mental disorder.

B. *Need for Medical Evidence:* We must establish the existence of a medically determinable impairment(s) of the required duration by medical evidence consisting of symptoms, signs, and laboratory findings (including psychological test findings). Symptoms are your own description of your physical or mental impairment(s). Psychiatric signs are medically demonstrable phenomena that indicate specific psychological abnormalities, e.g., abnormalities of behavior, mood, thought, memory, orientation, development, or perception, as described by an appropriate medical source. Symptoms and signs generally cluster together to constitute recognizable mental disorders described in the listings. The symptoms and signs may be intermittent or continuous depending on the nature of the disorder.

C. *Assessment of Severity:* We measure severity according to the functional limitations imposed by your medically determinable mental impairment(s). We assess functional limitations using the four criteria in paragraph B of the listings: Activities of daily living; social functioning; concentration, persistence, or pace; and episodes of decompensation. Where we use "marked" as a standard for measuring the degree of limitation, it means more than moderate but less than extreme. A marked limitation may arise when several activities or functions are impaired, or

even when only one is impaired, as long as the degree of limitation is such as to interfere seriously with your ability to function independently, appropriately, effectively, and on a sustained basis. See §§ 404.1520a and 416.920a.

1. *Activities of daily living* include adaptive activities such as cleaning, shopping, cooking, taking public transportation, paying bills, maintaining a residence, caring appropriately for your grooming and hygiene, using telephones and directories, and using a post office. In the context of your overall situation, we assess the quality of these activities by their independence, appropriateness, effectiveness, and sustainability. We will determine the extent to which you are capable of initiating and participating in activities independent of supervision or direction.

We do not define "marked" by a specific number of activities of daily living in which functioning is impaired, but by the nature and overall degree of interference with function. For example, if you do a wide range of activities of daily living, we may still find that you have a marked limitation in your daily activities if you have serious difficulty performing them without direct supervision, or in a suitable manner, or on a consistent, useful, routine basis, or without undue interruptions or distractions.

2. *Social functioning* refers to your capacity to interact independently, appropriately, effectively, and on a sustained basis with other individuals. Social functioning includes the ability to get along with others, such as family members, friends, neighbors, grocery clerks, landlords, or bus drivers. You may demonstrate impaired social functioning by, for example, a history of altercations, evictions, firings, fear of strangers, avoidance of interpersonal relationships, or social isolation. You may exhibit strength in social functioning by such things as your ability to initiate social contacts with others, communicate clearly with others, or interact and actively participate in group activities. We also need to consider cooperative behaviors, consideration for others, awareness of others' feelings, and social maturity. Social functioning in work situations may involve interactions with the public, responding appropriately to persons in authority (e.g., supervisors), or cooperative behaviors involving coworkers.

We do not define "marked" by a specific number of different behaviors in which social functioning is impaired, but by the nature and overall degree of interference with function. For example, if you are highly antagonistic, uncooperative, or hostile but are tolerated by local storekeepers, we may nevertheless find that you have a marked limitation in social functioning because that behavior is not acceptable in other social contexts.

3. *Concentration, persistence, or pace* refers to the ability to sustain focused attention and concentration sufficiently long to permit the timely and appropriate completion of tasks commonly found in work settings. Limitations in concentration, persistence, or pace are best observed in work settings, but may also be reflected by limitations in other settings. In addition, major limitations in this area can often be assessed through clinical examination or psychological testing. Wherever possible, however, a mental status examination or psychological test data should be supplemented by other available evidence.

On mental status examinations, concentration is assessed by tasks such as having you subtract serial sevens or serial threes from 100. In psychological tests of intelligence or memory, concentration is assessed through tasks requiring short-term memory or through tasks that must be completed within established time limits.

In work evaluations, concentration, persistence, or pace is assessed by testing your ability to sustain work using appropriate production standards, in either real or simulated work tasks (e.g., filing index cards, locating telephone numbers, or disassembling and reassembling objects). Strengths and weaknesses in areas of concentration and attention can be discussed in terms of your ability to work at a consistent pace for acceptable periods of time and until a task is completed, and your ability to repeat sequences of action to achieve a goal or an objective.

We must exercise great care in reaching conclusions about your ability or inability to complete tasks under the stresses of employment during a normal workday or workweek based on a time-limited mental status examination or psychological testing by a clinician, or based on your ability to complete tasks in other settings that are less demanding, highly structured, or more supportive. We must assess your ability to complete tasks by evaluating all the evidence, with an emphasis on how independently, appropriately, and effectively you are able to complete tasks on a sustained basis.

We do not define "marked" by a specific number of tasks that you are unable to complete, but by the nature and overall degree of interference with function. You may be able to sustain attention and persist at simple tasks but may still have difficulty with complicated tasks. Deficiencies that are apparent only in performing complex procedures or tasks would not satisfy the intent of this paragraph B criterion. However, if you can complete many simple tasks, we may nevertheless find that you have a marked limitation in concentration, persistence, or pace if you cannot complete these tasks without extra supervision or assistance, or in accordance with quality and accuracy standards, or at a consistent pace without an unreasonable number and length of rest periods, or without undue interruptions or distractions.

4. *Episodes of decompensation* are exacerbations or temporary increases in symptoms or signs accompanied by a loss of adaptive functioning, as manifested by difficulties in performing activities of daily living, maintaining social relationships, or maintaining concentration, persistence, or pace. Episodes of decompensation may be demonstrated by an exacerbation in symptoms or signs that would ordinarily require increased treatment or a less stressful situation (or a combination of the two). Episodes of decompensation may be inferred from medical records showing significant alteration in medication; or documentation of the need for a more structured psychological support system (e.g., hospitalizations, placement in a halfway house, or a highly structured and directing household); or other relevant information in the record about the existence, severity, and duration of the episode.

The term *repeated episodes of decompensation, each of extended duration* in these listings means three episodes within 1 year, or an average of once every 4 months, each lasting for at least 2 weeks. If you have experienced more frequent episodes of shorter duration or less frequent episodes of longer duration, we must use judgment to determine if the duration and functional effects of the episodes are of equal severity and may be used to substitute for the listed finding in a determination of equivalence.

D. *Documentation:* The evaluation of disability on the basis of a mental disorder requires sufficient evidence to (1) establish the presence of a medically determinable mental impairment(s), (2) assess the degree of functional limitation the impairment(s) imposes, and (3) project the probable duration of the impairment(s). See §§ 404.1512 and 416.912 for a discussion of what we mean by "evidence" and how we will assist you in developing your claim. Medical evidence must be sufficiently complete and detailed as to symptoms, signs, and laboratory findings to

permit an independent determination. In addition, we will consider information from other sources when we determine how the established impairment(s) affects your ability to function. We will consider all relevant evidence in your case record.

1. *Sources of evidence*.

a. *Medical evidence*. There must be evidence from an acceptable medical source showing that you have a medically determinable mental impairment. See §§ 404.1508, 404.1513, 416.908, and 416.913. We will make every reasonable effort to obtain all relevant and available medical evidence about your mental impairment(s), including its history, and any records of mental status examination, psychological testing, and hospitalizations and treatment. Whenever possible, and appropriate, medical source evidence should reflect the medical source's considerations of information from you and other concerned persons who are aware of your activities of daily living; social functioning; concentration, persistence, or pace; or episodes of decompensation.

Also, in accordance with standard clinical practice, any medical source assessment of your mental functioning should take into account any sensory, motor, or communication abnormalities, as well as your cultural and ethnic background.

b. *Information from the individual*. Individuals with mental impairments can often provide accurate descriptions of their limitations. The presence of a mental impairment does not automatically rule you out as a reliable source of information about your own functional limitations. When you have a mental impairment and are willing and able to describe your limitations, we will try to obtain such information from you. However, you may not be willing or able to fully or accurately describe the limitations resulting from your impairment(s). Thus, we will carefully examine the statements you provide to determine if they are consistent with the information about, or general pattern of, the impairment as described by the medical and other evidence, and to determine whether additional information about your functioning is needed from you or other sources.

c. *Other information*. Other professional health care providers (e.g., psychiatric nurse, psychiatric social worker) can normally provide valuable functional information, which should be obtained when available and needed. If necessary, information should also be obtained from nonmedical sources, such as family members and others who know you, to supplement the record of your functioning in order to establish the consistency of the medical evidence and longitudinality of impairment severity, as discussed in 12.00D2. Other sources of information about functioning include, but are not limited to, records from work evaluations and rehabilitation progress notes.

2. *Need for longitudinal evidence*. Your level of functioning may vary considerably over time. The level of your functioning at a specific time may seem relatively adequate or, conversely, rather poor. Proper evaluation of your impairment(s) must take into account any variations in the level of your functioning in arriving at a determination of severity over time. Thus, it is vital to obtain evidence from relevant sources over a sufficiently long period prior to the date of adjudication to establish your impairment severity.

3. *Work attempts*. You may have attempted to work or may actually have worked during the period of time pertinent to the determination of disability. This may have been an independent attempt at work or it may have been in conjunction with a community mental health or sheltered program, and it may have been of either short or long duration. Information concerning your behavior during any attempt to work and the circumstances surrounding termination of your work effort are particularly useful in determining your ability or inability to function in a work setting.

In addition, we should also examine the degree to which you require special supports (such as those provided through supported employment or transitional employment programs) in order to work.

4. *Mental status examination*. The mental status examination is performed in the course of a clinical interview and is often partly assessed while the history is being obtained. A comprehensive mental status examination generally includes a narrative description of your appearance, behavior, and speech; thought process (e.g., loosening of associations); thought content (e.g., delusions); perceptual abnormalities (e.g., hallucinations); mood and affect (e.g., depression, mania); sensorium and cognition (e.g., orientation, recall, memory, concentration, fund of information, and intelligence); and judgment and insight. The individual case facts determine the specific areas of mental status that need to be emphasized during the examination.

5. *Psychological testing*.

a. Reference to a "standardized psychological test" indicates the use of a psychological test measure that has appropriate validity, reliability, and norms, and is individually administered by a qualified specialist. By "qualified," we mean the specialist must be currently licensed or certified in the State to administer, score, and interpret psychological tests and have the training and experience to perform the test.

b. Psychological tests are best considered as standardized sets of tasks or questions designed to elicit a range of responses. Psychological testing can also provide other useful data, such as the specialist's observations regarding your ability to sustain attention and concentration, relate appropriately to the specialist, and perform tasks independently (without prompts or reminders). Therefore, a report of test results should include both the objective data and any clinical observations.

c. The salient characteristics of a good test are: (1) Validity, i.e., the test measures what it is supposed to measure; (2) reliability, i.e., the consistency of results obtained over time with the same test and the same individual; (3) appropriate normative data, i.e., individual test scores can be compared to test data from other individuals or groups of a similar nature, representative of that population; and (4) wide scope of measurement, i.e., the test should measure a broad range of facets/aspects of the domain being assessed. In considering the validity of a test result, we should note and resolve any discrepancies between formal test results and the individual's customary behavior and daily activities.

6. *Intelligence tests*.

a. The results of standardized intelligence tests may provide data that help verify the presence of mental retardation or organic mental disorder, as well as the extent of any compromise in cognitive functioning. However, since the results of intelligence tests are only part of the overall assessment, the narrative report that accompanies the test results should comment on whether the IQ scores are considered valid and consistent with the developmental history and the degree of functional limitation.

b. Standardized intelligence test results are essential to the adjudication of all cases of mental retardation that are not covered under the provisions of 12.05A. Listing 12.05A may be the basis for adjudicating cases where the results of standardized intelligence tests are unavailable, e.g., where your condition precludes formal standardized testing.

c. Due to such factors as differing means and standard deviations, identical IQ scores obtained from different tests do not always reflect a similar degree of intellectual functioning. The IQ scores in 12.05 reflect values from tests of general intelligence that have a mean of 100 and a standard deviation of 15; e.g., the Wechsler series. IQs obtained from standardized tests that deviate from a mean of 100 and a standard deviation of 15 require conversion to a percentile rank so that we can determine the actual degree of limitation reflected by the IQ scores. In cases where more than one IQ is customarily derived from the test administered, e.g., where verbal, performance, and full scale IQs are provided in the Wechsler series, we use the lowest of these in conjunction with 12.05.

d. Generally, it is preferable to use IQ measures that are wide in scope and include items that test both verbal and performance abilities. However, in special circumstances, such as the assessment of individuals with sensory, motor, or communication abnormalities, or those whose culture and background are not principally English-speaking, measures such as the Test of Nonverbal Intelligence, Third Edition (TONI-3), Leiter International Performance Scale-Revised (Leiter-R), or Peabody Picture Vocabulary Test-Third Edition (PPVT-III) may be used.

e. We may consider exceptions to formal standardized psychological testing when an individual qualified by training and experience to perform such an evaluation is not available, or in cases where appropriate standardized measures for your social, linguistic, and cultural background are not available. In these cases, the best indicator of severity is often the level of adaptive functioning and how you perform activities of daily living and social functioning.

7. *Personality measures and projective testing techniques*. Results from standardized personality measures, such as the Minnesota Multiphasic Personality Inventory-Revised (MMPI-II), or from projective types of techniques, such as the Rorschach and the Thematic Apperception Test (TAT), may provide useful data for evaluating several types of mental disorders. Such test results may be useful for disability evaluation when corroborated by other evidence, including results from other psychological tests and information obtained in the course of the clinical evaluation, from treating and other medical sources, other professional health care providers, and nonmedical sources. Any inconsistency between test results and clinical history and observation should be explained in the narrative description.

8. *Neuropsychological assessments*. Comprehensive neuropsychological examinations may be used to establish the existence and extent of compromise of brain function, particularly in cases involving organic mental disorders. Normally, these examinations include assessment of cerebral dominance, basic sensation and perception, motor speed and coordination, attention and concentration, visual-motor function, memory across verbal and visual modalities, receptive and expressive speech, higher-order linguistic operations, problem-solving, abstraction ability, and general intelligence. In addition, there should be a clinical interview geared toward evaluating pathological features known to occur frequently in neurological disease and trauma; e.g., emotional lability, abnormality of mood, impaired impulse control, passivity and apathy, or inappropriate social behavior. The specialist performing the examination may administer one of the commercially available comprehensive neuropsychological batteries, such as the Luria-Nebraska or the Halstead-Reitan, or a battery of tests selected as relevant to the suspected brain dysfunction. The specialist performing the examination must be properly trained in this area of neuroscience.

9. *Screening tests*. In conjunction with clinical examinations, sources may report the results of screening tests; i.e., tests used for gross determination of level of functioning. Screening instruments may be useful in uncovering potentially serious impairments, but often must be

supplemented by other data. However, in some cases the results of screening tests may show such obvious abnormalities that further testing will clearly be unnecessary.

10. *Traumatic brain injury (TBI)*. In cases involving TBI, follow the documentation and evaluation guidelines in 11.00F.

11. *Anxiety disorders*. In cases involving agoraphobia and other phobic disorders, panic disorders, and posttraumatic stress disorders, documentation of the anxiety reaction is essential. At least one detailed description of your typical reaction is required. The description should include the nature, frequency, and duration of any panic attacks or other reactions, the precipitating and exacerbating factors, and the functional effects. If the description is provided by a medical source, the reporting physician or psychologist should indicate the extent to which the description reflects his or her own observations and the source of any ancillary information. Statements of other persons who have observed you may be used for this description if professional observation is not available.

12. *Eating disorders*. In cases involving anorexia nervosa and other eating disorders, the primary manifestations may be mental or physical, depending upon the nature and extent of the disorder. When the primary functional limitation is physical; e.g., when severe weight loss and associated clinical findings are the chief cause of inability to work, we may evaluate the impairment under the appropriate physical body system listing. Of course, we must also consider any mental aspects of the impairment, unless we can make a fully favorable determination or decision based on the physical impairment(s) alone.

E. *Chronic mental impairments*. Particular problems are often involved in evaluating mental impairments in individuals who have long histories of repeated hospitalizations or prolonged outpatient care with supportive therapy and medication. For instance, if you have chronic organic, psychotic, and affective disorders, you may commonly have your life structured in such a way as to minimize your stress and reduce your symptoms and signs. In such a case, you may be much more impaired for work than your symptoms and signs would indicate. The results of a single examination may not adequately describe your sustained ability to function. It is, therefore, vital that we review all pertinent information relative to your condition, especially at times of increased stress. We will attempt to obtain adequate descriptive information from all sources that have treated you in the time period relevant to the determination or decision.

F. *Effects of structured settings*. Particularly in cases involving chronic mental disorders, overt symptomatology may be controlled or attenuated by psychosocial factors such as placement in a hospital, halfway house, board and care facility, or other environment that provides similar structure. Highly structured and supportive settings may also be found your home. Such settings may greatly reduce the mental demands placed on you. With lowered mental demands, overt symptoms and signs of the underlying mental disorder may be minimized. At the same time, however, your ability to function outside of such a structured or supportive setting may not have changed. If your symptomatology is controlled or attenuated by psychosocial factors, we must consider your ability to function outside of such highly structured settings. For these reasons, identical paragraph C criteria are included in 12.02, 12.03, and 12.04. The paragraph C criterion of 12.06 reflects the uniqueness of agoraphobia, an anxiety disorder manifested by an overwhelming fear of leaving the home.

G. *Effects of medication*. We must give attention to the effects of medication on your symptoms, signs, and ability to function. While drugs used to modify psychological functions and mental states may control certain primary manifestations of a mental disorder, e.g., hallucinations,

impaired attention, restlessness, or hyperactivity, such treatment may not affect all functional limitations imposed by the mental disorder. In cases where overt symptomatology is attenuated by the use of such drugs, particular attention must be focused on the functional limitations that may persist. We will consider these functional limitations in assessing impairment severity. See the paragraph C criteria in 12.02, 12.03, 12.04, and 12.06. Drugs used in the treatment of some mental illnesses may cause drowsiness, blunted affect, or other side effects involving other body systems. We will consider such side effects when we evaluate the overall severity of your impairment. Where adverse effects of medications contribute to the impairment severity and the impairment(s) neither meets nor is equivalent in severity to any listing but is nonetheless severe, we will consider such adverse effects in the RFC assessment.

H. *Effects of treatment*. With adequate treatment some individuals with chronic mental disorders not only have their symptoms and signs ameliorated, but they also return to a level of function close to the level of function they had before they developed symptoms or signs of their mental disorders. Treatment may or may not assist in the achievement of a level of adaptation adequate to perform sustained SGA. See the paragraph C criteria in 12.02, 12.03, 12.04, and 12.06.

I. *Technique for reviewing evidence in mental disorders claims to determine the level of impairment severity*. We have developed a special technique to ensure that we obtain, consider, and properly evaluate all the evidence we need to evaluate impairment severity in claims involving mental impairment(s). We explain this technique in §§ 404.1520a and 416.920a.

12.01 Category of Impairments - Mental

12.02 ***Organic Mental Disorders***: Psychological or behavioral abnormalities associated with a dysfunction of the brain. History and physical examination or laboratory tests demonstrate the presence of a specific organic factor judged to be etiologically related to the abnormal mental state and loss of previously acquired functional abilities.

The required level of severity for these disorders is met when the requirements in both A and B are satisfied, or when the requirements in C are satisfied.

A. Demonstration of a loss of specific cognitive abilities or affective changes and the medically documented persistence of at least one of the following:

1. Disorientation to time and place; or

2. Memory impairment, either short-term (inability to learn new information), intermediate, or long-term (inability to remember information that was known sometime in the past); or

3. Perceptual or thinking disturbances (e.g., hallucinations, delusions); or

4. Change in personality; or

5. Disturbance in mood; or

6. Emotional lability (e.g., explosive temper outbursts, sudden crying, etc.) and impairment in impulse control; or

7. Loss of measured intellectual ability of at least 15 I.Q. points from premorbid levels or overall impairment index clearly within the severely impaired range on neuropsychological testing, e.g., Luria-Nebraska, Halstead-Reitan, etc;

AND

B. Resulting in at least two of the following:

1. Marked restriction of activities of daily living; or

2. Marked difficulties in maintaining social functioning; or

3. Marked difficulties in maintaining concentration, persistence, or pace; or

4. Repeated episodes of decompensation, each of extended duration;

OR

C. Medically documented history of a chronic organic mental disorder of at least 2 years' duration that has caused more than a minimal limitation of ability to do basic work activities, with symptoms or signs currently attenuated by medication or psychosocial support, and one of the following:

1. Repeated episodes of decompensation, each of extended duration; or

2. A residual disease process that has resulted in such marginal adjustment that even a minimal increase in mental demands or change in the environment would be predicted to cause the individual to decompensate; or

3. Current history of 1 or more years' inability to function outside a highly supportive living arrangement, with an indication of continued need for such an arrangement.

12.03 ***Schizophrenic, Paranoid and Other Psychotic Disorders***: Characterized by the onset of psychotic features with deterioration from a previous level of functioning.

The required level of severity for these disorders is met when the requirements in both A and B are satisfied, or when the requirements in C are satisfied.

A. Medically documented persistence, either continuous or intermittent, of one or more of the following:

1. Delusions or hallucinations; or

2. Catatonic or other grossly disorganized behavior; or

3. Incoherence, loosening of associations, illogical thinking, or poverty of content of speech if associated with one of the following:

a. Blunt affect; or

b. Flat affect; or

c. Inappropriate affect;

OR

4. Emotional withdrawal and/or isolation;

AND

B. Resulting in at least two of the following:

1. Marked restriction of activities of daily living; or

2. Marked difficulties in maintaining social functioning; or

3. Marked difficulties in maintaining concentration, persistence, or pace; or

4. Repeated episodes of decompensation, each of extended duration;

OR

C. Medically documented history of a chronic schizophrenic, paranoid, or other psychotic disorder of at least 2 years' duration that has caused more than a minimal limitation of ability to do basic work activities, with symptoms or signs currently attenuated by medication or psychosocial support, and one of the following:

1. Repeated episodes of decompensation, each of extended duration; or

2. A residual disease process that has resulted in such marginal adjustment that even a minimal increase in mental demands or change in the environment would be predicted to cause the individual to decompensate; or

3. Current history of 1 or more years' inability to function outside a highly supportive living arrangement, with an indication of continued need for such an arrangement.

12.04 ***Affective Disorders***: Characterized by a disturbance of mood, accompanied by a full or partial manic or depressive syndrome. Mood refers to a prolonged emotion that colors the whole psychic life; it generally involves either depression or elation.

The required level of severity for these disorders is met when the requirements in both A and B are satisfied, or when the requirements in C are satisfied.

A. Medically documented persistence, either continuous or intermittent, of one of the following:

1. Depressive syndrome characterized by at least four of the following:

a. Anhedonia or pervasive loss of interest in almost all activities; or

b. Appetite disturbance with change in weight; or

c. Sleep disturbance; or

d. Psychomotor agitation or retardation; or

e. Decreased energy; or

f. Feelings of guilt or worthlessness; or

g. Difficulty concentrating or thinking; or

h. Thoughts of suicide; or

i. Hallucinations, delusions, or paranoid thinking; or

2. Manic syndrome characterized by at least three of the following:

a. Hyperactivity; or

b. Pressure of speech; or

c. Flight of ideas; or

d. Inflated self-esteem; or

e. Decreased need for sleep; or

f. Easy distractibility; or

g. Involvement in activities that have a high probability of painful consequences which are not recognized; or

h. Hallucinations, delusions or paranoid thinking; or

3. Bipolar syndrome with a history of episodic periods manifested by the full symptomatic picture of both manic and depressive syndromes (and currently characterized by either or both syndromes);

AND

B. Resulting in at least two of the following:

1. Marked restriction of activities of daily living; or

2. Marked difficulties in maintaining social functioning; or

3. Marked difficulties in maintaining concentration, persistence, or pace; or

4. Repeated episodes of decompensation, each of extended duration;

OR

C. Medically documented history of a chronic affective disorder of at least 2 years' duration that has caused more than a minimal limitation of ability to do basic work activities, with symptoms or signs currently attenuated by medication or psychosocial support, and one of the following:

1. Repeated episodes of decompensation, each of extended duration; or

2. A residual disease process that has resulted in such marginal adjustment that even a minimal increase in mental demands or change in the environment would be predicted to cause the individual to decompensate; or

3. Current history of 1 or more years' inability to function outside a highly supportive living arrangement, with an indication of continued need for such an arrangement.

12.05 ***Mental Retardation****:* Mental retardation refers to significantly sub-average general intellectual functioning with deficits in adaptive functioning initially manifested during the developmental period; i.e., the evidence demonstrates or supports onset of the impairment before age 22.

The required level of severity for this disorder is met when the requirements in A, B, C, or D are satisfied.

A. Mental incapacity evidenced by dependence upon others for personal needs (e.g., toileting, eating, dressing, or bathing) and inability to follow directions, such that the use of standardized measures of intellectual functioning is precluded;

OR

B. A valid verbal, performance, or full scale IQ of 59 or less;

OR

C. A valid verbal, performance, or full scale IQ of 60 through 70 and a physical or other mental impairment imposing an additional and significant work-related limitation of function;

OR

D. A valid verbal, performance, or full scale IQ of 60 through 70, resulting in at least two of the following:

1. Marked restriction of activities of daily living; or

2. Marked difficulties in maintaining social functioning; or

3. Marked difficulties in maintaining concentration, persistence, or pace; or

4. Repeated episodes of decompensation, each of extended duration.

12.06 ***Anxiety-Related Disorders***: In these disorders anxiety is either the predominant disturbance or it is experienced if the individual attempts to master symptoms; for example, confronting the dreaded object or situation in a phobic disorder or resisting the obsessions or compulsions in obsessive compulsive disorders.

The required level of severity for these disorders is met when the requirements in both A and B are satisfied, or when the requirements in both A and C are satisfied.

A. Medically documented findings of at least one of the following:

1. Generalized persistent anxiety accompanied by three out of four of the following signs or symptoms:

a. Motor tension; or

b. Autonomic hyperactivity; or

c. Apprehensive expectation; or

d. Vigilance and scanning; or

2. A persistent irrational fear of a specific object, activity, or situation which results in a compelling desire to avoid the dreaded object, activity, or situation; or

3. Recurrent severe panic attacks manifested by a sudden unpredictable onset of intense apprehension, fear, terror and sense of impending doom occurring on the average of at least once a week; or

4. Recurrent obsessions or compulsions which are a source of marked distress; or

5. Recurrent and intrusive recollections of a traumatic experience, which are a source of marked distress;

AND

B. Resulting in at least two of the following:

1. Marked restriction of activities of daily living; or

2. Marked difficulties in maintaining social functioning; or

3. Marked difficulties in maintaining concentration, persistence, or pace; or

4. Repeated episodes of decompensation, each of extended duration.

OR

C. Resulting in complete inability to function independently outside the area of one's home.

12.07 ***Somatoform Disorders***: Physical symptoms for which there are no demonstrable organic findings or known physiological mechanisms.

The required level of severity for these disorders is met when the requirements in both A and B are satisfied.

A. Medically documented by evidence of one of the following:

1. A history of multiple physical symptoms of several years duration, beginning before age 30, that have caused the individual to take medicine frequently, see a physician often and alter life patterns significantly; or

2. Persistent nonorganic disturbance of one of the following:

a. Vision, or

b. Speech; or

c. Hearing; or

d. Use of a limb; or

e. Movement and its control (e.g., coordination disturbance, psychogenic seizures, akinesia, dyskinesia; or

f. Sensation (e.g., diminished or heightened).

3. Unrealistic interpretation of physical signs or sensations associated with the preoccupation or belief that one has a serious disease or injury;

AND

B. Resulting in at least two of the following:

1. Marked restriction of activities of daily living; or

2. Marked difficulties in maintaining social functioning; or

3. Marked difficulties in maintaining concentration, persistence, or pace; or

4. Repeated episodes of decompensation, each of extended duration.

12.08 ***Personality Disorders***: A personality disorder exists when personality traits are inflexible and maladaptive and cause either significant impairment in social or occupational functioning or subjective distress. Characteristic features are typical of the individual's long-term functioning and are not limited to discrete episodes of illness.

The required level of severity for these disorders is met when the requirements in both A and B are satisfied.

A. Deeply ingrained, maladaptive patterns of behavior associated with one of the following:

1. Seclusiveness or autistic thinking; or

2. Pathologically inappropriate suspiciousness or hostility; or

3. Oddities of thought, perception, speech and behavior; or

4. Persistent disturbances of mood or affect; or

5. Pathological dependence, passivity, or aggressivity; or

6. Intense and unstable interpersonal relationships and impulsive and damaging behavior;

AND

B. Resulting in at least two of the following:

1. Marked restriction of activities of daily living; or

2. Marked difficulties in maintaining social functioning; or

3. Marked difficulties in maintaining concentration, persistence, or pace; or

4. Repeated episodes of decompensation, each of extended duration.

12.09 ***Substance Addiction Disorders***: Behavioral changes or physical changes associated with the regular use of substances that affect the central nervous system.

The required level of severity for these disorders is met when the requirements in any of the following (A through I) are satisfied.

A. Organic mental disorders. Evaluate under 12.02.

B. Depressive syndrome. Evaluate under 12.04.

C. Anxiety disorders. Evaluate under 12.06.

D. Personality disorders. Evaluate under 12.08.

E. Peripheral neuropathies. Evaluate under 11.14.

F. Liver damage. Evaluate under 5.05.

G. Gastritis. Evaluate under 5.04.

H. Pancreatitis. Evaluate under 5.08.

I. Seizures. Evaluate under 11.02 or 11.03.

12.10 ***Autistic disorder and other pervasive developmental disorders***: Characterized by qualitative deficits in the development of reciprocal social interaction, in the development of verbal and nonverbal communication skills, and in imaginative activity. Often, there is a markedly restricted repertoire of activities and interests, which frequently are stereotyped and repetitive.

The required level of severity for these disorders is met when the requirements in both A and B are satisfied.

A. Medically documented findings of the following:

1. For autistic disorder, all of the following:

a. Qualitative deficits in reciprocal social interaction; and

b. Qualitative deficits in verbal and nonverbal communication and in imaginative activity; and

c. Markedly restricted repertoire of activities and interests;

OR

2. For other pervasive developmental disorders, both of the following:

a. Qualitative deficits in reciprocal social interaction; and

b. Qualitative deficits in verbal and nonverbal communication and in imaginative activity;

AND

B. Resulting in at least two of the following:

1. Marked restriction of activities of daily living; or

2. Marked difficulties in maintaining social functioning; or

3. Marked difficulties in maintaining concentration, persistence, or pace; or

4. Repeated episodes of decompensation, each of extended duration.

13.00 Malignant Neoplastic Diseases

A. *What impairments do these listings cover?* We use these listings to evaluate all malignant neoplasms except certain neoplasms associated with human immunodeficiency virus (HIV) infection. We use the criteria in 14.08E to evaluate carcinoma of the cervix, Kaposi's sarcoma, lymphoma, and squamous cell carcinoma of the anus if you also have HIV infection.

B. *What do we consider when we evaluate malignant neoplastic diseases under these listings?* We consider factors such as the:

1. Origin of the malignancy.

2. Extent of involvement.

3. Duration, frequency, and response to antineoplastic therapy. Antineoplastic therapy means surgery, irradiation, chemotherapy, hormones, immunotherapy, or bone marrow or stem cell transplantation. When we refer to surgery as an antineoplastic treatment, we mean surgical excision for treatment, not for diagnostic purposes.

4. Effects of any post-therapeutic residuals.

C. *How do we apply these listings?* We apply the criteria in a specific listing to a malignancy originating from that specific site.

D. *What evidence do we need?*

1. We need medical evidence that specifies the type, extent, and site of the primary, recurrent, or metastatic lesion. When the primary site cannot be identified, we will use evidence documenting the site(s) of metastasis to evaluate the impairment under 13.27.

2. For operative procedures, including a biopsy or a needle aspiration, we generally need a copy of both the:

a. Operative note.

b. Pathology report.

3. When we cannot get these documents, we will accept the summary of hospitalization(s) or other medical reports. This evidence should include details of the findings at surgery and, whenever appropriate, the pathological findings.

4. In some situations we may also need evidence about recurrence, persistence, or progression of the malignancy, the response to therapy, and any significant residuals. (See 13.00G.)

E. *When do we need longitudinal evidence?*

1. *Tumors with distant metastases.* We generally do not need longitudinal evidence for tumors that have metastasized beyond the regional lymph nodes because these tumors usually meet the requirements of a listing. Exceptions are for tumors with distant metastases that are expected to respond to antineoplastic therapy. For these exceptions, we usually need a longitudinal record of 3 months after therapy starts to determine whether the intended effect of therapy has been achieved and is likely to persist.

2. *Other malignancies*. When there are no distant metastases, many of the listings require that we consider your response to initial antineoplastic therapy; that is, the initial planned treatment regimen. This therapy may consist of a single modality or a combination of modalities (multimodal) given in close proximity as a unified whole, and is usually planned before any treatment(s) is initiated. Examples of multimodal therapy include:

a. Surgery followed by chemotherapy or radiation.

b. Chemotherapy followed by surgery.

c. Chemotherapy and concurrent radiation.

3. *Types of treatment*. Whenever the initial planned therapy is a single modality, enough time must pass to allow a determination about whether the therapy will achieve its intended effect. If the treatment fails, the failure will often happen within 6 months after treatment starts, and there will often be a change in the treatment regimen. Whenever the initial planned therapy is multimodal, a determination about the effectiveness of the therapy usually cannot be made until the effects of all the planned modalities can be determined. In some cases, we may need to defer adjudication until the effectiveness of therapy can be assessed. However, we do not need to defer adjudication to determine whether the therapy will achieve its intended effect if we can make a fully favorable determination or decision based on the length and effects of therapy, or the residuals of the malignancy or therapy (see 13.00G).

F. *How do we evaluate impairments that do not meet one of the malignant neoplastic diseases listings?*

1. These listings are only examples of malignant neoplastic diseases that we consider severe enough to prevent you from doing any gainful activity. If your severe impairment(s) does not meet the criteria of any of these listings, we must also consider whether you have an impairment(s) that meets the criteria of a listing in another body system.

2. If you have a severe medically determinable impairment(s) that does not meet a listing, we will determine whether your impairment(s) medically equals a listing. (See §§404.1526 and 416.926.) If your impairment(s) does not meet or medically equal a listing, you may or may not have the residual functional capacity to engage in substantial gainful activity. In that situation, we proceed to the fourth, and, if necessary, the fifth steps of the sequential evaluation process in §§404.1520 and 416.920. If you are an adult, we use the rules in §§404.1594 and 416.994, as appropriate, when we decide whether you continue to be disabled.

G. *How do we consider the effects of therapy?*

1. *How we consider the effects of therapy under the listings*. In many cases, malignancies meet listing criteria only if the therapy does not achieve the intended effect: the malignancy persists, progresses, or recurs despite treatment. However, as explained in the following paragraphs, we will not delay adjudication if we can make a fully favorable determination or decision based on the evidence in the case record.

2. *Effects can vary widely*.

a. Because the therapy and its toxicity may vary widely, we consider each case on an individual basis. We will request a specific description of the therapy, including these items:

i. Drugs given.

ii. Dosage.

iii. Frequency of drug administration.

iv. Plans for continued drug administration.

v. Extent of surgery.

vi. Schedule and fields of radiation therapy.

b. We will also request a description of the complications or adverse effects of therapy, such as the following:

i. Continuing gastrointestinal symptoms.

ii. Persistent weakness.

iii. Neurological complications.

iv. Cardiovascular complications.

v. Reactive mental disorders.

3. *Effects of therapy may change*. Because the severity of the adverse effects of antineoplastic therapy may change during treatment, enough time must pass to allow us to evaluate the therapy's effect. The residual effects of treatment are temporary in most instances. But, on occasion, the effects may be disabling for a consecutive period of at least 12 months.

4. *When the initial antineoplastic therapy is effective*. We evaluate any post-therapeutic residual impairment(s) not included in these listings under the criteria for the affected body system. We must consider any complications of therapy. When the residual impairment(s) does not meet or medically equal a listing, we must consider its affect on your ability to do substantial gainful activity.

H. *How long do we consider your impairment to be disabling?*

1. In some listings, we specify that we will consider your impairment to be disabling until a particular point in time (for example, at least 18 months from the date of diagnosis). We may consider your impairment to be disabling beyond this point the medical and other evidence justifies it.

2. When a listing does not contain such a specification, we will consider an impairment(s) that meets or medically equals a listing in this body system to be disabling until at least 3 years after onset of complete remission. When the impairment(s) has been in complete remission for at least 3 years, that is, the original tumor and any metastases have not been evident for at least 3 years, the impairment(s) will no longer meet or medically equal the criteria of a listing in this body system.

3. Following the appropriate period, we will consider any residuals, including residuals of the malignancy or therapy (see 13.00G), in determining whether you are disabled.

I. *What do these terms in the listings mean?*

1. *Inoperable*: Surgery is thought to be of no therapeutic value or the surgery cannot be performed. Examples of when surgery cannot be performed include a tumor that is too large or that invades crucial structures, or an intolerance of anesthesia or surgery due to other medical conditions. This term does not include situations in which the tumor could have been surgically removed but another method of treatment was chosen; for example, an attempt at organ preservation. The determination whether a tumor is inoperable usually occurs before attempts to shrink the tumor with chemotherapy or radiation.

2. *Unresectable*: The operation was performed, but the malignant tumor was not removed. This term includes situations in which a tumor is incompletely resected or the surgical margins are positive.

3. *Persistent*: Failure to achieve a complete remission.

4. *Progressive:* The malignancy became more extensive after treatment.

5. *Recurrent, relapse*: A malignancy that had been in complete remission or entirely removed by surgery has returned.

J. *Can we establish the existence of a disabling impairment prior to the date of the evidence that shows the malignancy satisfies the criteria of a listing?* Yes. We will consider factors such as:

1. The type of malignancy and its location.

2. The extent of involvement when the malignancy was first demonstrated.

3. Your symptoms.

K. *How do we evaluate specific malignant neoplastic diseases*?

1. *Lymphoma*.

a. Many low grade or indolent (non-aggressive) lymphomas are controlled by well-tolerated treatment modalities, although they may produce intermittent symptoms and signs. Therefore, we may defer adjudication of these cases for an appropriate period after initiation of therapy to determine whether the therapy will achieve its intended effect. (See 13.00E3.) For a low grade or indolent lymphoma, the intended effect of therapy is usually stability of the disease process. When stability has been achieved, we will assess severity on the basis of the extent of involvement of other organ systems and residuals from therapy.

b. A change in therapy for low grade or indolent lymphoma is usually an indicator that the therapy is not achieving its intended effect. However, it does not indicate this if the change is based on your (or your physician's) choice rather than a failure to achieve stability. If the therapy is changed due solely to choice, the requirements of listing 13.05A2a are not met.

c. We consider Hodgkin's disease that recurs more than 12 months after completing initial antineoplastic therapy to be a new disease rather than a recurrence.

2. *Leukemia*.

a. *Acute leukemia*. The initial diagnosis of acute leukemia, including the accelerated or blast phase of chronic myelogenous (granulocytic) leukemia, is based upon definitive bone marrow examination. Additional diagnostic information is based on chromosomal analysis, cytochemical and surface marker studies on the abnormal cells, or other methods consistent with the prevailing state of medical knowledge and clinical practice. Recurrent disease must be documented by peripheral blood, bone marrow, or cerebrospinal fluid examination. The initial and follow-up pathology reports should be included.

b. *Chronic myelogenous leukemia (CML)*. The diagnosis of CML should be based upon documented granulocytosis, including immature forms such as differentiated or undifferentiated myelocytes and myeloblasts, and a chromosomal analysis that demonstrates the Philadelphia chromosome. In the absence of a chromosomal analysis, or if the Philadelphia chromosome is not present, the diagnosis may be made by other methods consistent with the prevailing state of medical knowledge and clinical practice.

c. *Chronic lymphocytic leukemia*.

i. The diagnosis of chronic lymphocytic leukemia (CLL) must be documented by evidence of a chronic lymphocytosis of at least 10,000/mm^3 for 3 months or longer, or other acceptable diagnostic techniques consistent with the prevailing state of medical knowledge and clinical practice.

ii. We evaluate the complications and residual impairment(s) from CLL under the appropriate listings, such as 13.05A2, 7.02, and 7.15.

d. *Elevated white cell count*. In cases of chronic leukemia (either myelogenous or lymphocytic), an elevated white cell count, in itself, is not ordinarily a factor in determining the severity of the impairment.

3. *Macroglobulinemia or heavy chain disease*. The diagnosis of these diseases must be confirmed by protein electrophoresis or immunoelectrophoresis. We evaluate the resulting impairment(s) under the criteria of 7.02, 7.06, 7.08, or any other affected body system.

4. *Bilateral primary breast cancer*. We evaluate bilateral primary breast cancer (synchronous or metachronous) under 13.10A, which covers local primary disease, and not as a primary disease that has metastasized.

5. *Carcinoma-in-situ*. Carcinoma-in-situ, or preinvasive carcinoma, usually responds to treatment. When we use the term "carcinoma" in these listings, it does not include carcinoma-in-situ.

6. *Brain tumors*. We use the criteria in 13.13 to evaluate malignant brain tumors. We will evaluate any complications of malignant brain tumors, such as resultant neurological or psychological impairments, under the criteria for the affected body system. We evaluate benign brain tumors under 11.05.

L. *How do we evaluate malignant neoplastic diseases treated by bone marrow or stem cell transplantation?* Bone marrow or stem cell transplantation is performed for a variety of malignant neoplastic diseases.

1. *Acute leukemia (including T-cell lymphoblastic lymphoma) or accelerated or blast phase of CML*. If you undergo bone marrow or stem cell transplantation for any of these disorders, we will consider you to be disabled until at least 24 months from the date of diagnosis or relapse, or at least 12 months from the date of transplantation, whichever is later.

2. *Lymphoma, multiple myeloma, or chronic phase of CML*. If you undergo bone marrow or stem cell transplantation for any of these disorders, we will consider you to be disabled until at least 12 months from the date of transplantation.

3. *Other malignancies*. We will evaluate any other malignant neoplastic disease treated with bone marrow or stem cell transplantation under 13.28, regardless of whether there is another listing that addresses that impairment. The length of time we will consider you to be disabled depends on whether you undergo allogeneic or autologous transplantation.

a. *Allogeneic bone marrow or stem cell transplantation*. If you undergo allogeneic transplantation (transplantation from an unrelated donor or a related donor other than an identical twin), we will consider you to be disabled until at least 12 months from the date of transplantation.

b. *Autologous bone marrow or stem cell transplantation*. If you undergo autologous transplantation (transplantation of your own cells or cells from your identical twin (syngeneic transplantation)), we will consider you to be disabled until at least 12 months from the date of the first treatment under the treatment plan that includes transplantation. The first treatment usually refers to the initial therapy given to prepare you for transplantation.

4. *Evaluating disability after the appropriate time period has elapsed*. We consider any residual impairment(s), such as complications arising from:

a. Graft-versus-host (GVH) disease.

b. Immunosuppressant therapy, such as frequent infections.

c. Significant deterioration of other organ systems.

13.01 Category of Impairments, Malignant Neoplastic Diseases

13.02 ***Soft tissue tumors of the head and neck (except salivary glands—13.06—and thyroid gland – 13.07).***

A. Inoperable or unresectable.

OR

B. Persistent disease following initial multimodal antineoplastic therapy.

OR

C. Recurrent disease following initial antineoplastic therapy, except local vocal cord recurrence.

OR

D. With metastases beyond the regional lymph nodes.

OR

E. Soft tissue tumors of the head and neck not addressed in A-D, with multimodal antineoplastic therapy. Consider under a disability until at least 18 months from the date of diagnosis. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

13.03 ***Skin.***

A. Sarcoma or carcinoma with metastases to or beyond the regional lymph nodes.

OR

B. Melanoma, with either 1 or 2:

1. Recurrent after wide excision (except an additional primary melanoma at a different site, which is not considered to be recurrent disease).

2. Palpable nodal metastases or metastases to adjacent skin (satellite lesions) or elsewhere.

13.04 ***Soft tissue sarcoma.***

A. With regional or distant metastases.

OR

B. Persistent or recurrent following initial antineoplastic therapy.

13.05 ***Lymphoma (including mycosis fungoides, but excluding T-cell lymphoblastic lymphoma--13.06***). (See 13.00K1 and 13.00K2c.)

A. Non-Hodgkin's lymphoma, as described in 1 or 2:

1. Intermediate or high-grade lymphoma persistent or recurrent following initial antineoplastic therapy.

2. Low-grade or indolent lymphoma requiring initiation of more than one antineoplastic treatment regimen within a consecutive 12-month period. Consider under a disability from at least the date of initiation of the treatment regimen that failed within 12 months.

OR

B. Hodgkin's disease with failure to achieve clinically complete remission, or recurrent disease within 12 months of completing initial antineoplastic therapy.
OR

C. With bone marrow or stem cell transplantation. Consider under a disability until at least 12 months from the date of transplantation. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

13.06 ***Leukemia.*** (See 13.00K2.)

A. Acute leukemia (including T-cell lymphoblastic lymphoma). Consider under a disability until at least 24 months from the date of diagnosis or relapse, or at least 12 months from the date of bone marrow or stem cell transplantation, whichever is later. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

OR

B. Chronic myelogenous leukemia, as described in 1 or 2:

1. Accelerated or blast phase. Consider under a disability until at least 24 months from the date of diagnosis or relapse, or at least 12 months from the date of bone marrow or stem cell transplantation, whichever is later. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

2. Chronic phase, as described in a or b:

a. Consider under a disability until at least 12 months from the date of bone marrow or stem cell transplantation. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

b. Progressive disease following initial antineoplastic therapy.

13.07 ***Multiple myeloma (confirmed by appropriate serum or urine protein electrophoresis and bone marrow findings)***.

A. Failure to respond or progressive disease following initial antineoplastic therapy.

OR

B. With bone marrow or stem cell transplantation. Consider under a disability until at least 12 months from the date of transplantation. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

13.08 ***Salivary glands--***carcinoma or sarcoma with metastases beyond the regional lymph nodes.

13.09 ***Thyroid Gland.***

A. Anaplastic (undifferentiated) carcinoma.

OR

B. Carcinoma with metastases beyond the regional lymph nodes progressive despite radioactive iodine therapy.

13.10 ***Breast (except sarcoma—13.04)*** (See 13.00K4.)

A. Locally advanced carcinoma (inflammatory carcinoma, tumor of any size with direct extension to the chest wall or skin, tumor of any size with metastases to the ipsilateral internal mammary nodes.

B. Carcinoma with distant metastases.

OR

C. Recurrent carcinoma, except local recurrence that remits with antineoplastic therapy.

13. 11 ***Skeletal system***--carcinoma or sarcoma.

A. Inoperable or unresectable.

OR

B. Recurrent tumor (except local recurrence) after initial antineoplastic therapy.

OR

C. With distant metastases.

OR

D. All other tumors originating in bone with multimodal antineoplastic therapy. Consider under a disability for 12 months from the date of diagnosis. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

13.12 ***Maxilla, orbit, or temporal fossa.***

A. Sarcoma or carcinoma of any type with regional or distant metastases.

OR

B. Carcinoma of the antrum with extension into the orbit or ethmoid or sphenoid sinus.

OR

C. Tumors with extension to the base of the skull, orbit, meninges, or sinuses.

13.13 ***Nervous system.*** (See 13.00K6.)

A. Central nervous system neoplasms (brain and spinal cord), as described in 1 or 2:

1. Highly malignant tumors, such as Grades III and IV astrocytomas, glioblastoma multiforme, ependymoblastoma, medulloblastoma or other primitive neuroectodermal tumors (PNETs) with documented metastases, diffuse intrinsic brain stem gliomas, or primary sarcomas.

2. Any central nervous system neoplasm progressive or recurrent following initial antineoplastic therapy.

OR

B. Peripheral nerve or spinal root neoplasm, as described in 1 or 2:

1. Metastatic.

2. Progressive or recurrent following initial antineoplastic therapy.

13.14 ***Lungs.***

A. Non-small-cell carcinoma--inoperable, unresectable, recurrent, or metastatic disease to or beyond the hilar nodes.

OR

B. Small-cell (oat cell) carcinoma.

13.15 ***Pleura or Mediastinum.***

A. Malignant mesothelioma of pleura.

OR

B. Tumors of the mediastinum, as described in 1 or 2:

1. With metastases to or beyond the regional lymph nodes.

2. Persistent or recurrent following initial antineoplastic therapy.

13.16 ***Esophagus or stomach.***

A. Carcinoma or sarcoma of the esophagus.

OR

B. Carcinoma or sarcoma of the stomach, as described in 1 or 2:

1. Inoperable, unresectable, extending to surrounding structures, or recurrent.

2. With metastases to or beyond the regional lymph nodes.

13.17 ***Small intestine***--carcinoma, sarcoma, or carcinoid.

A. Inoperable, unresectable, or recurrent.

OR

B. With metastases beyond the regional lymph nodes.

13.18 ***Large intestine (from ileocecal valve to and including anal canal).***

A. Adenocarcinoma that is inoperable, unresectable, or recurrent.

OR

B. Squamous cell carcinoma of the anus, recurrent after surgery.

OR

C. With metastases beyond the regional lymph nodes.

13.19 ***Liver or Gallbladder--*** tumors of the liver, gallbladder, or bile ducts.

13.20 ***Pancreas.***

A. Carcinoma (except islet cell carcinoma).

OR

B. Islet cell carcinoma that is inoperable or unresectable and physiologically active.

13.21 ***Kidneys, adrenal glands, or ureters--***carcinoma***.***

A. Inoperable, unresectable, or recurrent.

OR

B. With metastases to or beyond the regional lymph nodes.

13.22 ***Urinary bladder***--carcinoma.

A. With infiltration beyond the bladder wall.

OR

B. Recurrent after total cystectomy.

OR

C. Inoperable or unresectable.

OR

D. With metastases to or beyond the regional lymph nodes.

13.23 ***Cancers of the female genital tract***--carcinoma or sarcoma**.**

A. Uterus (corpus), as described in 1, 2, or 3:

1. Invading adjoining organs.

2. With metastases to or beyond the regional lymph nodes.

3. Persistent or recurrent following initial antineoplastic therapy.

OR

B. Uterine cervix, as described in 1 or 2:

1. Extending to the pelvic wall, lower portion of the vagina, or adjacent or distant organs.

2. Persistent or recurrent following initial antineoplastic therapy.

OR

C. Vulva, as described in 1, 2, or 3:

1. Invading adjoining organs.

2. With metastases to or beyond the regional lymph nodes.

3. Persistent or recurrent following initial antineoplastic therapy.

OR

D. Fallopian tubes, as described in 1 or 2:

1. Extending to the serosa or beyond.

2. Persistent or recurrent following initial antineoplastic therapy.

OR

E. Ovaries, as described in 1 or 2:

1. All tumors except germ-cell tumors, with at least one of the following:

a. Tumor extension beyond the pelvis; for example, tumor implants on peritoneal, omental, or bowel surfaces.

b. Metastases to or beyond the regional lymph nodes.

c. Ruptured ovarian capsule, tumor on the serosal surface of the ovary, ascites with malignant cells, or positive peritoneal washings.

d. Recurrent following initial antineoplastic therapy.

2. Germ-cell tumors--progressive or recurrent following initial antineoplastic therapy.

13.24 ***Prostate gland***—carcinoma.

A. Progressive or recurrent despite initial hormonal intervention.

OR

B. With visceral metastases.

13.25 ***Testicles***—tumor with metastatic disease progressive or recurrent following initial chemotherapy.

13.26 ***Penis***--carcinoma with metastases to or beyond the regional lymph nodes.

13.27 ***Primary site unknown after appropriate search for primary***—metastatic carcinoma or sarcoma, except for solitary squamous cell carcinoma in the neck.

13.28 ***Malignant neoplastic diseases treated by bone marrow or stem cell transplantation***. (See 13.00L.)

A. Allogeneic transplantation. Consider under a disability until at least 12 months from the date of transplantation. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

OR

B. Autologous transplantation. Consider under a disability until at least 12 months from the date of the first treatment under the treatment plan that includes transplantation. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

14.00 Immune System

A. Listed disorders include impairments involving deficiency of one or more components of the immune system (i.e., antibody-producing B cells; a number of different types of cells associated with cell-mediated immunity including T-lymphocytes, macrophages and monocytes; and components of the complement system).

B. Dysregulation of the immune system may result in the development of a connective tissue disorder. Connective tissue disorders include several chronic multisystem disorders that differ in their clinical manifestation, course, and outcome. They generally evolve and persist for months or years, may result in loss of functional abilities, and may require long-term, repeated evaluation and management.

The documentation needed to establish the existence of a connective tissue disorder is medical history, physical examination, selected laboratory studies, appropriate medically acceptable imaging and, in some instances, tissue biopsy. Medically acceptable imaging includes, but is not limited to, x-ray imaging, computerized axial tomography (CAT scan) or magnetic resonance imaging (MRI), with or without contrast material, myelography, and radionuclear bone scans. "Appropriate" means that the technique used is the proper one to support the evaluation and diagnosis of the impairment. However, the Social Security Administration will not purchase diagnostic tests or procedures that may involve significant risk, such as biopsies or angiograms. Generally, the existing medical evidence will contain this information.

A longitudinal clinical record of at least 3 months demonstrating active disease despite prescribed treatment during this period with the expectation that the disease will remain active for 12 months is necessary for assessment of severity and duration of impairment.

To permit appropriate application of a listing, the specific diagnostic features that should be documented in the clinical record for each of the disorders are summarized for systemic lupus erythematosus (SLE), systemic vasculitis, systemic sclerosis and scleroderma, polymyositis or dermatomyositis, and undifferentiated connective tissue disorders and the inflammatory arthritides.

In addition to the limitations caused by the connective tissue disorder *per se*, the chronic adverse effects of treatment (e.g., corticosteroid-related ischemic necrosis of bone) may result in functional loss.

These disorders may preclude performance of any gainful activity by reason of serious loss of function because of disease affecting a single organ or body system, or lesser degrees of functional loss because of disease affecting two or more organs/body systems associated with significant constitutional symptoms and signs of severe fatigue, fever, malaise, weight loss, and joint pain and stiffness. We use the term "severe" in these listings to describe medical severity; the term does not have the same meaning as it does when we use it in connection with a finding at the second step of the sequential evaluation processes in §§ 404.1520, 416.920, and 416.924.

1. Systemic lupus erythematosus (14.02) - This disease is characterized clinically by constitutional symptoms and signs (e.g., fever, fatigability, malaise, weight loss), multisystem involvement, and frequently, anemia, leukopenia, or thrombocytopenia. Immunologically, an array of circulating serum auto-antibodies can occur, but are highly variable in pattern. Generally,

the medical evidence will show that patients with this disease will fulfill The 1982 Revised Criteria for the Classification of Systemic Lupus Erythematosus of the American College of Rheumatology. (Tan, E.M., et al., Arthritis Rheum. 25:11271-1277, 1982).

2. Systemic vasculitis (14.03) - This disease occurs acutely in association with adverse drug reactions, certain chronic infections and, occasionally, malignancies. More often it is idiopathic and chronic. There are several clinical patterns, including classical polyarteritis nodosa, aortic arch arteritis, giant cell arteritis, Wegener's granulomatosis, and vasculitis associated with other connective tissue disorders (e.g., rheumatoid arthritis, SLE, Sjogren's syndrome, cryoglobulinemia). Cutaneous vasculitis may or may not be associated with systemic involvement and the patterns of vascular and ischemic involvement are highly variable. The diagnosis is confirmed by angiography or tissue biopsy when the disease is suspected clinically. Most patients who are stated to have this disease will have the results of the confirmatory angiogram or biopsy in their medical records.

3. Systemic sclerosis and scleroderma (14.04) - These disorders constitute a spectrum of disease in which thickening of the skin is the clinical hallmark. Raynaud's phenomena, often severe and progressive, are especially frequent and may be the peripheral manifestation of a generalized vasospastic abnormality in the heart, lungs, and kidneys. The CREST syndrome (calcinosis, Raynaud's phenomena, esophageal dysmotility, sclerodactyly, and telangiectasia) is a variant that may slowly progress to the generalized process, systemic sclerosis, over years. In addition to skin and blood vessels, the major organ/body system involvement includes the gastrointestinal tract, lungs, heart, kidneys, and muscle. Although arthritis can occur, joint dysfunction results primarily from soft tissue/cutaneous thickening, fibrosis, and contractures.

4. Polymyositis or dermatomyositis (14.05) - This disorder is primarily an inflammatory process in striated muscle, which can occur alone or in association with other connective tissue disorders or malignancy. Weakness, and less frequently, pain and tenderness of the proximal limb-girdle musculature are the cardinal manifestations. Involvement of the cervical muscles, the cricopharyngeals, the intercostals, and diaphragm may occur in those with listing level disease.

Weakness of the pelvic girdle, as contemplated in Listing 14.05.A, may result in significant difficulty climbing stairs or rising from a chair without use of the arms. Proximal limb weakness in the upper extremities may result in inability to lift objects, and interference with dressing and combing hair. Weakness of anterior neck flexors may impair the ability to lift the head from the pillow in bed. The diagnosis is supported by elevated serum
muscle enzymes (creatine phosphokinase (CPK), aminotransferases, aldolase), characteristic abnormalities on electromyography, and myositis on muscle biopsy.

5. Undifferentiated connective tissue disorder (14.06) - This listing includes syndromes with clinical and immunologic features of several connective tissue disorders, but that do not satisfy the criteria for any of the disorders described; for instance, the individual may have clinical features of systemic lupus erythematosus and systemic vasculitis and the serologic findings of rheumatoid arthritis. It also includes overlap syndromes with clinical features of more than one established connective tissue disorder. For example, the individual may have features of both rheumatoid arthritis and scleroderma. The correct designation of this disorder is important for assessment of prognosis.

6. Inflammatory arthritis (14.09) includes a vast array of disorders that differ in cause, course, and outcome. For example, inflammatory spondyloarthropathies include ankylosing spondylitis, Reiter's syndrome and other reactive arthropathies, psoriatic arthropathy, Behçet's disease, and

Whipple's disease, as well as undifferentiated spondylitis. Inflammatory arthritis of peripheral joints likewise comprises many disorders, including rheumatoid arthritis, Sjögren's syndrome, psoriatic arthritis, crystal deposition disorders, and Lyme disease. Clinically, inflammation of major joints may be the dominant problem causing difficulties with ambulation or fine and gross movements, or the arthritis may involve other joints or cause less restriction of ambulation or other movements but be complicated by extra-articular features that cumulatively result in serious functional deficit. When persistent deformity without ongoing inflammation is the dominant feature of the impairment, it should be evaluated under 1.02, or, if there has been surgical reconstruction, 1.03.

a. In 14.09A, the term *major joints* refers to the major peripheral joints, which are the hip, knee, shoulder, elbow, wrist-hand, and ankle-foot, as opposed to other peripheral joints (e.g., the joints of the hand or forefoot) or axial joints (i.e., the joints of the spine.) The wrist and hand are considered together as one major joint, as are the ankle and foot. Since only the ankle joint, which consists of the juncture of the bones of the lower leg (tibia and
fibula) with the hindfoot (tarsal bones), but not the forefoot, is crucial to weight bearing, the ankle and foot are considered separately in evaluating weight bearing.

b. The terms *inability to ambulate effectively* and *inability to perform fine and gross movements effectively* in 14.09A have the same meaning as in 1.00B2b and 1.00B2c and must have lasted, or be expected to last, for at least 12 months.

c. Inability to ambulate effectively is implicit in 14.09B. Even though individuals who demonstrate the findings of 14.09B will not ordinarily require bilateral upper limb assistance, the required ankylosis of the cervical or dorsolumbar spine will result in an extreme loss of the ability to see ahead, above, and to the side.

d. As in 14.02 through 14.06, extra-articular features of an inflammatory arthritis may satisfy the criteria for a listing in an involved extra-articular body system. Such impairments may be found to meet a criterion of 14.09C. Extra-articular impairments of lesser severity should be evaluated under 14.09D and 14.09E. Commonly occurring extra-articular impairments include keratoconjunctivitis sicca, uveitis, iridocyclitis, pleuritis, pulmonary fibrosis or nodules, restrictive lung disease, pericarditis, myocarditis, cardiac arrhythmias, aortic valve insufficiency, coronary arteritis, Raynaud's phenomena, systemic vasculitis, amyloidosis of the kidney, chronic anemia, thrombocytopenia, hypersplenism with compromised immune competence (Felty's syndrome), peripheral neuropathy, radiculopathy, spinal cord or cauda equina compression with sensory and motor loss, and heel enthesopathy with functionally limiting pain.

e. The fact that an individual is dependent on steroids, or any other drug, for the control of inflammatory arthritis is, in and of itself, insufficient to find disability. Advances in the treatment of inflammatory connective tissue disease and in the administration of steroids for its treatment have corrected some of the previously disabling consequences of continuous steroid use. Therefore, each case must be evaluated on its own merits, taking into consideration the severity of the underlying impairment and any adverse effects of treatment.

C. Allergic disorders (e.g., asthma or atopic dermatitis) are discussed and evaluated under the appropriate listing of the affected body system.

D. Human immunodeficiency virus (HIV) infection.

1. HIV infection is caused by a specific retrovirus and may be characterized by susceptibility to one or more opportunistic diseases, cancers, or other conditions, as described in 14.08. Any individual with HIV infection, including one with a diagnosis of acquired immunodeficiency syndrome (AIDS), may be found disabled under this listing if his or her impairment meets any of the criteria in 14.08 or is of equivalent severity to any impairment in 14.08.

2. *Definitions*. In 14.08, the terms "resistant to treatment" "recurrent" and "disseminated" have the same general meaning as used by the medical community. The precise meaning of any of these terms will depend upon the
specific disease or condition in question, the body system affected, the usual course of the disorder and its treatment, and the other circumstances of the case.

"Resistant to treatment" means that a condition did not respond adequately to an appropriate course of treatment. Whether a response is adequate, or a course of treatment appropriate, will depend on the facts of the particular case.

"Recurrent" means that a condition that responded adequately to an appropriate course of treatment has returned after a period of remission or regression. The extent of response (or remission) and the time periods involved will depend on the facts of the particular case.

"Disseminated" means that a condition is spread widely over a considerable area or body system(s). The type and extent of the spread will depend on the specific disease.

As used in 14.08I, "significant involuntary weight loss" does not correspond to a specific minimum amount or percentage of weight loss. Although, for purposes of this listing, an involuntary weight loss of at least 10 percent of baseline is always considered significant, loss of less than 10 percent may or may not be significant, depending on the individual's baseline weight and body habitus. (For example, a 7-pound weight loss in a 100-pound female who is 63 inches tall might be considered significant; but a 14-pound weight loss in a 200-pound female who is the same height might not be significant.)

3. Documentation of HIV infection. The medical evidence must include documentation of HIV infection. Documentation may be by laboratory evidence or by other generally acceptable methods consistent with the prevailing state of medical knowledge and clinical practice.

a. Documentation of HIV infection by definitive diagnosis. A definitive diagnosis of HIV infection is documented by one or more of the following laboratory tests:

i. A serum specimen that contains HIV antibodies. HIV antibodies are usually detected by a screening test. The most commonly used screening test is the ELISA. Although this test is highly sensitive, it may yield false positive results. Therefore, positive results from an ELISA must be confirmed by a more definitive test (e.g., Western Blot, immunofluorescence assay).

ii. A specimen that contains HIV antigen (e.g., serum specimen, lymphocyte culture, or cerebrospinal fluid (CSF) specimen).

iii. Other test(s) that are highly specific for detection of HIV (e.g., polymerase chain reaction (PCR)), or that are acceptable methods of detection consistent with the prevailing state of medical knowledge.

When laboratory testing for HIV infection has been performed, every reasonable effort must be made to obtain reports of the results of that testing.

Individuals who have HIV infection or other disorders of the immune system may undergo tests to determine T-helper lymphocyte (CD4) counts. The extent of immune depression correlates with the level or rate of decline of the CD4 count. In general, when the CD4 count is 200/mm^3 or less (14 percent or less), the susceptibility to opportunistic disease is considerably increased. However, a reduced CD4 count alone does not establish a definitive diagnosis of HIV infection, or document the severity or functional effects of HIV infection.

b. Other acceptable documentation of HIV infection.

HIV infection may also be documented without the definitive laboratory evidence described in paragraph a, provided that such documentation is consistent with the prevailing state of medical knowledge and clinical practice and is consistent with the other evidence. If no definitive laboratory evidence is available, HIV infection may be documented by the medical history, clinical and laboratory findings, diagnosis(es) indicated in the medical evidence. For example, a diagnosis of HIV infection will be accepted without definitive laboratory evidence if the individual has an opportunistic disease (e.g., toxoplasmosis of the brain, pneumocystis carinii pneumonia (PCP)) predictive of a defect in cell-mediated immunity, and there is no other known cause of diminished resistance to that disease (e.g., long-term steroid treatment, lymphoma). In such cases, every reasonable effort must be made to obtain full details of the history, medical findings, and results of testing.

4. Documentation of the manifestations of HIV infection. The medical evidence must also include documentation of the manifestations of HIV infection. Documentation may be by laboratory evidence or by other generally acceptable methods consistent with the prevailing state of medical knowledge and clinical practice.

a. Documentation of the manifestations of HIV infection by definitive diagnosis.

The definitive method of diagnosing opportunistic diseases or conditions that are manifestations of HIV infection is by culture, serological test, or microscopic examination of biopsied tissue or other material (e.g., bronchial washings). Therefore, every reasonable effort must be made to obtain specific laboratory evidence of an opportunistic disease or other condition whenever this information is available. If a histological or other test has been performed, the evidence should include a copy of the appropriate report. If the report is not obtainable, the summary of hospitalization or a report from the treating source should include details of the findings and results of the diagnostic studies (including radiographic studies) or microscopic examination of the appropriate tissues or body fluids.

Although a reduced CD4 lymphocyte count may show that there is an increased susceptibility to opportunistic infections and diseases (see 14.001) 3a, above), that alone does not establish the presence, severity, or functional effects of a manifestation of HIV infection.

b. Other acceptable documentation of the manifestations of HIV infection.

Manifestations of HIV infection may also be documented without the definitive laboratory evidence described in paragraph a, provided that such documentation is consistent with the prevailing state of medical knowledge and clinical practice and is consistent with the other evidence. If no definitive laboratory evidence is available, manifestations of HIV infection may

be documented by medical history, clinical and laboratory findings, and diagnosis(es) indicated in the medical evidence. In such cases, every reasonable effort must be made to obtain full details of the history, medical findings, and results of testing.

Documentation of cytomegalovirus (CMV) disease (14.08D) presents special problems because diagnosis requires identification of viral inclusion bodies or a positive culture from the affected organ, and the absence of any other infectious agent. A positive serology test identifies infection with the virus, but does not confirm a disease process.

With the exception of chorioretinitis (which may be diagnosed by an ophthalmologist), documentation of CMV disease requires confirmation by biopsy or other generally acceptable methods consistent with the prevailing state of medical knowledge and clinical practice.

5. Manifestations specific to women. Most women with severe immunosuppression secondary to HIV infection exhibit the typical opportunistic infections and other conditions, such as pneumocystis carinii pneumonia (PCP), candida esophagitis, wasting syndrome, cryptococcosis, and toxoplasmosis. However HIV infection may have different manifestations, in women than in men. Adjudicators must carefully scrutinize the medical evidence and be alert to the variety of medical conditions specific to or common in women with HIV infection that may affect their ability to function in the workplace.

Many of these manifestations (e.g., vulvovaginal candidiasis, pelvic inflammatory disease) occur in women with or without HIV infection, but can be more severe or resistant to treatment, or occur more frequently in a woman whose immune system is suppressed. Therefore, when evaluating the claim of a woman with HIV infection, it is important to consider gynecologic and other problems specific to women, including any associated symptoms (e.g., pelvic pain), in assessing the severity of the impairment and resulting functional limitations. Manifestations of HIV infection in women may be evaluated under the specific criteria (e.g., cervical cancer under 14.08E), under an applicable general category (e.g., pelvic inflammatory disease under 14.08A5) or, in appropriate cases, under 14.08N.

6. *Evaluation*. The criteria in 14.08 do not describe the full spectrum of diseases or conditions manifested by individuals with HIV infection. As in any case, consideration must be given to whether an individual's impairment(s) meets or equals in severity any other listing in appendix 1 of subpart P (e.g., a neoplastic disorder listed in 13.00ff). Although 14.08 includes cross-references to other listings for the more common manifestations of HIV infection, other listings may apply.

In addition, the impact of all impairments, whether or not related to HIV infection, must be considered. For example, individuals with HIV infection may manifest signs and symptoms of a mental impairment (e.g., anxiety, depression), or of another physical impairment. Medical evidence should include documentation of all physical and mental impairments, and the impairment(s) should be evaluated not only under the relevant listing(s) in 14.08, but under any other appropriate listing(s).

It is also important to remember that individuals with HIV infection, like all other individuals, are evaluated under the full five-step sequential evaluation process described in Section 404.1520 and Section 416.920. If an individual with HIV infection is working and engaging in substantial gainful activity (SGA), or does not have a severe impairment, the case will be decided at the first or second step of the sequential evaluation process, and does not require evaluation under these listings. For an individual with HIV infection who is not engaging in SGA and has a severe

impairment, but whose impairment(s) does not meet or equal in severity the criteria of a listing, evaluation must proceed through the final steps of the sequential evaluation process (or, as appropriate, the steps in the medical improvement review standard) before any conclusion can be reached on the issue of disability.

7. Effect of treatment. Medical treatment must be considered in terms of its effectiveness in ameliorating the signs, symptoms, and laboratory abnormalities of the specific disorder, or of the HIV infection itself (e.g. antiretroviral agents) and in terms of any side effects of treatment that may further impair the individual.

Response to treatment and adverse or beneficial consequences of treatment may vary widely. For example, an individual with HIV infection who develops pneumonia or tuberculosis may respond to the same antibiotic regimen used in treating individuals without HIV infection, but another individual with HIV infection may not respond to the same regimen. Therefore, each case must be considered on an individual basis, along with the effects of treatment on the individual's ability to function.

A specific description of the drugs or treatment given (including surgery), dosage, frequency of administration, and a description of the complications or response to treatment should be obtained. The effects of treatment may be temporary or long term. As such, the decision regarding the impact of treatment should be based on a sufficient period of treatment to permit proper consideration.

8. Functional criteria. Paragraph N of 14.08 establishes standards for evaluating manifestations of HIV infection that do not meet the requirements listed in 14.08A-M. Paragraph N is applicable for manifestations that are not listed in 14.08A-M, as well as those listed in 14.08A-M that do not meet the criteria of any of the rules in 14.08A-M.

For individuals with HIV infection evaluated under 14.08N, listing-level severity will be assessed in terms of the functional limitations imposed by the impairment. The full impact of signs, symptoms, and laboratory findings on the claimant's ability to function must be considered. Important factors to be considered in evaluating the functioning of individuals with HIV infection include, but are not limited to: symptoms, such as fatigue and pain; characteristics of the illness, such as the frequency and duration of manifestations or periods of exacerbation and remission in the disease course; and the functional impact of treatment for the disease, including the side effects of medication.

As used in 14.08N, "repeated" means that the conditions occur on an average of 3 times a year, or once every 4 months, each lasting 2 weeks or more; or the conditions do not last for 2 weeks but occur substantially more frequently than 3 times in a year or once every 4 months; or they occur less often than an average of 3 times a year or once every 4 months but last substantially longer than 2 weeks.

To meet the criteria in 14.08N, an individual with HIV infection must demonstrate a marked level of restriction in one of three general areas of functioning: activities of daily living; social functioning; and difficulties in completing tasks due to deficiencies in concentration, persistence, or pace. Functional restrictions may result from the impact of the disease process itself on mental or physical functioning, or both. This could result from extended or intermittent symptoms, such as depression, fatigue, or pain, resulting in a limitation of the ability to concentrate, to persevere at a task, or to perform the task at an acceptable rate of speed. Limitations may also result from the side effects of medication.

When "marked" is used as a standard for measuring the degree of functional limitation, it means more than moderate, but less than extreme. A marked limitation does not represent a quantitative measure of the individual's ability to do an activity for a certain percentage of the time. A marked limitation may be present when several activities or functions are impaired or even when only one is impaired. However, an individual need not be totally precluded from performing an activity to have a marked limitation, as long as the degree of limitation is such as to seriously interfere with the ability to function independently, appropriately, and effectively. The term "marked" does not imply that the impaired individual is confined to bed, hospitalized, or in a nursing home.

Activities of daily living include, but are not limited to, such activities as doing, household chores, grooming and hygiene, using a post office, taking public transportation, and paying bills. An individual with HIV infection who, because of symptoms such as pain imposed by the illness or its treatment, is not able to maintain a household or take public transportation on a sustained basis or without assistance (even though he or she is able to perform some self-care activities) would have marked limitation of activities of daily living.

Social functioning includes the capacity to interact appropriately and communicate effectively with others. An individual with HIV infection who, because of symptoms or a pattern of exacerbation and remission caused by the illness or its treatment, cannot engage in social interaction on a sustained basis (even though he or she is able to communicate with close friends or relatives) would have marked difficulty maintaining social functioning.

Completing tasks in a timely manner involves the ability to sustain concentration, persistence, or pace to permit timely completion of tasks commonly found in work settings. An individual with HIV infection who, because of HIV-related fatigue or other symptoms, is unable to sustain concentration or pace adequate to complete simple work-related tasks (even though he or she is able to do routine activities of daily living) would have marked difficulty completing tasks.

14.01 Category of Impairments, Immune System

14.02 ***Systemic lupus erythematosus***. Documented as described in 14.00B 1, with:

A. One of the following:

1. Joint involvement, as described under the criteria in 1.00; or

2. Muscle involvement, as described under the criteria in 14.05; or

3. Ocular involvement, as described under the criteria in 2.00ff; or

4. Respiratory involvement, as described under the criteria in 3.00ff; or

5. Cardiovascular involvement, as described under the criteria in 4.00ff or 14.04D; or

6. Digestive involvement, as described under the criteria in 5.00ff; or

7. Renal involvement, as described under the criteria in 6.00ff; or

8. Hematologic involvement, as described under the criteria in 7.00ff; or

9. Skin involvement, as described under the criteria in 8.00ff; or

10. Neurological involvement, as described under the criteria in I 1.00ff, or

11. Mental involvement, as described under the criteria in 12.00ff.

Or

B. Lesser involvement of two or more organs/body systems listed in paragraph A, with significant, documented, constitutional symptoms and signs of severe fatigue, fever, malaise, and weight loss. At least one of the organs/body systems must be involved to at least a moderate level of severity.

14.03 ***Systemic vasculitis***. Documented as described in 14.00B2, including documentation by angiography or tissue biopsy, with:

A. Involvement of a single organ or body system, as described under the criteria in 14.02A.

Or

B. Lesser involvement of two or more organs/body systems listed in 14.02A, with significant, documented, constitutional symptoms and signs of severe fatigue, fever, malaise, and weight loss. At least one of the organs/body systems must be involved to at least a moderate level of severity.

14.04 ***Systemic sclerosis and scleroderma***. Documented as described in 14.00B3, with:

A. One of the following:

1. Muscle involvement, as described under the criteria in 14.05; or

2. Respiratory involvement, as described under the criteria in 3.00ff; or

3. Cardiovascular involvement, as described under the criteria in 4.00ff; or

4. Digestive involvement, as described under the criteria in 5.00ff, or

5. Renal involvement, as described under the criteria in 6.00ff.

Or

B. Lesser involvement of two or more organs/body systems listed in paragraph A, with significant, documented, constitutional symptoms and signs of severe fatigue, fever, malaise, and weight loss. At least one of the organs/body systems must be involved to at least a moderate level of severity.

Or

C. Generalized scleroderma with digital contractures.

Or

D. Severe Raynaud's phenomena, characterized by digital ulcerations, ischemia, or gangrene.

14.05 ***Polymyositis or dermatomyositis***. Documented as described in 14.00B4, with:

A. Severe proximal limb-girdle (shoulder and/or pelvic) muscle weakness, as described in 14.00B4.

Or

B. Less severe limb-girdle muscle weakness than in 14.05A, associated with cervical muscle weakness and one of the following to at least a moderate level of severity:

1. Impaired swallowing with dysphagia and episodes of aspiration due to cricopharyngeal weakness, or

2. Impaired respiration due to intercostal and diaphragmatic muscle weakness.

Or

C. If associated with malignant tumor, as described under the criteria in 13.00ff.

Or

D. If associated with generalized connective tissue disease, as described under the criteria in 14.02, 14.03, 14.04, or 14.06

14.06 ***Undifferentiated connective tissue disorder***. Documented as described in 14.00B5, and with impairment as described under the criteria in 14.02A, 14.02B, or 14.04.

14.07 ***Immunoglobulin deficiency syndromes or deficiencies of cell-mediated immunity, excepting HIV infection***. Associated with documented, recurrent severe infection occurring three or more times within a 5-month period.

14.08 ***Human Immunodeficiency Virus (HIV) infection***. With documentation as described in 14.00D3 and one of the following:

A. Bacterial infections:

1. Mycobacterial infection (e.g., caused by M. avium-intracellulare, M. kansasii, or M. tuberculosis) at site other than the lungs, skin, or cervical or hilar lymph nodes; or pulmonary tuberculosis resistant to treatment; or

2. Nocardiosis; or

3. Salmonella bacteremia, recurrent non-typhoid; or

4. Syphilis or neurosyphilis - evaluate sequelae under the criteria for the affected body system (e.g., 2.00 Special Senses and Speech, 4.00 Cardiovascular System, 11.00 Neurological); or
5. Multiple or recurrent bacterial infection(s), including pelvic inflammatory disease, requiring hospitalization or intravenous antibiotic treatment 3 or more times in 1 year.

Or

B. Fungal infections:

1. Aspergillosis; or

2. Candidiasis, at a site other than the skin, urinary tract, intestinal tract, or oral or vulvovaginal mucous membranes; or candidiasis involving the esophagus, trachea, bronchi, or lungs; or

3. Coccidioidomycosis, at a site other than the lungs or lymph nodes; or

4. Cryptococcosis, at a site other than the lungs (e.g., cryptococcal meningitis); or

5. Histoplasmosis, at a site other than the lungs or lymph nodes; or

6. Mucormycosis.

Or

C. Protozoan or helminthic infections:

1. Cryptosporidiosis, isosporiasis, or microsporidiosis, with diarrhea lasting for 1 month or longer; or

2. Pneumocystis carinii pneumonia or extrapulmonary pneumocystis carinii infection; or

3. Strongyloidiasis, extra-intestinal; or

4. Toxoplasmosis of an organ other than the liver, spleen, or lymph nodes.

Or

D. Viral infections:

1. Cytomegalovirus disease (documented as described in 14.00D4b) at a site other than the liver, spleen, or lymph nodes; or

2. Herpes simplex virus causing:

a. Mucocutaneous infection (e.g., oral, genital, perianal) lasting for 1 month or longer; or

b. Infection at a site other than the skin or mucous membranes (e.g., bronchitis, pneumonitis, esophagitis, or encephalitis); or

c. Disseminated infection; or

3. Herpes zoster, either disseminated or with multidermatomal eruptions that are resistant to treatment; or

4. Progressive multifocal leukoencephalopathy; or

5. Hepatitis, as described under the criteria in 5.05.

Or

E. Malignant neoplasms:

1. Carcinoma of the cervix, invasive, FIGO stage II and beyond; or

2. Kaposi's sarcoma with:

a. Extensive oral lesions; or

b. Involvement of the gastrointestinal tract, lungs, or other visceral organs; or

c. Involvement of the skin or mucous membranes, as described under the criteria in 14.08F; or

3. Lymphoma (e.g., primary lymphoma of the brain, Burkitt's lymphoma, immunoblastic sarcoma, other non-Hodgkins lymphoma, Hodgkin's disease); or

4. Squamous cell carcinoma of the anus.

Or

F. Conditions of the skin or mucous membranes (other than described in B2, D2, or D3, above), with extensive fungating or ulcerating lesions not responding to treatment (e.g., dermatological conditions such as eczema or psoriasis, vulvovaginal or other mucosal candida, condyloma caused by human papillomavirus, genital ulcerative disease), or evaluate under the criteria in 8.00ff.

Or

G. Hematologic abnormalities:

1. Anemia, as described under the criteria in 7.02; or

2. Granulocytopenia, as described under the criteria in 7.15; or

3. Thrombocytopenia, as described under the criteria in 7.06.

Or

H. Neurological abnormalities:

1. HIV encephalopathy, characterized by cognitive or motor dysfunction that limits function and progresses; or

2. Other neurological manifestations of HIV infection (e.g., peripheral neuropathy) as described under the criteria in 11.00ff.

Or

I. HIV wasting syndrome, characterized by involuntary weight loss of 10 percent or more of baseline (or other significant involuntary weight loss, as described in 14.00D2) and, in the absence of a concurrent illness that could explain the findings, either:

1. Chronic diarrhea with two or more loose stools daily lasting for 1 month or longer; or

2. Chronic weakness and documented fever greater than 38°C (100.40°F) for the majority of 1 month or longer.

Or

J. Diarrhea, lasting for 1 month or longer, resistant to treatment, and requiring intravenous hydration, intravenous alimentation, or tube feeding.

Or

K. Cardiomyopathy, as described under the criteria in 4.00ff or 11.04.

Or

L. Nephropathy, as described under the criteria in 6.00ff.

Or

M. One or more of the following infections (other than described in A-L, above), resistant to treatment or requiring hospitalization or intravenous treatment 3 or more times in I year (or evaluate sequelae under the criteria for the affected body system).

1. Sepsis; or

2. Meningitis; or

3. Pneumonia; or

4. Septic Arthritis; or

5. Endocarditis; or

6. Sinusitis documented by appropriate medically acceptable imaging.

Or

N. Repeated (as defined in 14.00D8) manifestations of HIV infection (including those listed in 14.08A-M, but without the requisite findings; e.g., carcinoma of the cervix not meeting the criteria in 14.08E, diarrhea not meeting the criteria in 14.08J, or other manifestations; e.g., oral hairy leukoplakia, myositis) resulting in significant, documented symptoms or signs (e.g., fatigue, fever, malaise, weight loss, pain, night sweats) and one of the following at the marked level (as defined in 14.00D8):

1. Restriction of activities of daily living; or

2. Difficulties in maintaining social functioning; or

3. Difficulties in completing tasks in a timely manner due to deficiencies in concentration, persistence, or pace.

14.09 ***Inflammatory Arthritis.*** Documented as described in 14.00B6, with one of the following:

A. History of joint pain, swelling, and tenderness, and signs on current physical examination of joint inflammation or deformity in two or more major joints resulting in inability to ambulate effectively or inability to perform fine and gross movements effectively, as defined in 14.00B6b and 1.00B2b and B2c;

or

B. Ankylosing spondylitis or other spondyloarthropathy, with diagnosis established by findings of unilateral or bilateral sacroiliitis (e.g., erosions or fusions), shown by appropriate medically acceptable imaging, with both:

1. History of back pain, tenderness, and stiffness, and

2. Findings on physical examination of ankylosis (fixation) of the dorsolumbar or cervical spine at 45^{o} or more of flexion measured from the vertical position (zero degrees);

or

C. An impairment as described under the criteria in 14.02A.

or

D. Inflammatory arthritis, with signs of peripheral joint inflammation on current examination, but with lesser joint involvement than in A and lesser extra-articular features than in C, and:

1. Significant, documented constitutional symptoms and signs (e.g., fatigue, fever, malaise, weight loss), and

2. Involvement of two or more organs/body systems (see 14.00B6d). At least one of the organs/body systems must be involved to at least a moderate level of severity.

or

E. Inflammatory spondylitis or other inflammatory spondyloarthropathies, with lesser deformity than in B and lesser extra-articular features than in C, with signs of unilateral or bilateral sacroiliitis on appropriate medically acceptable imaging; and with the extra-articular features described in 14.09D.